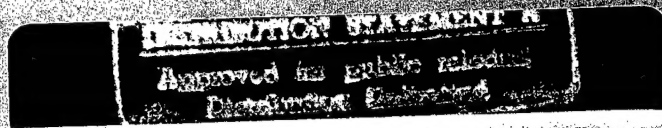


GAO

February 1997

TELEMEDICINE

Federal Strategy Is Needed to Guide Investments





United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

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February 14, 1997

The Honorable Curt Weldon
Chairman
The Honorable Owen B. Pickett
Ranking Minority Member
Subcommittee on Military Research
and Development
Committee on National Security
House of Representatives

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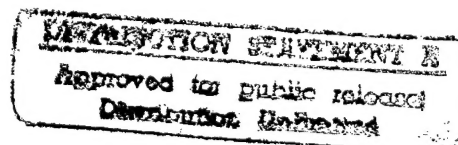
The Honorable John M. Spratt, Jr.
House of Representatives

This report responds to your request for information about the steps that the federal government needs to take to realize the full potential of telemedicine and achieve cooperation with the private sector. Specifically, we address the (1) scope of public and private telemedicine investments; (2) telemedicine strategies among the Department of Defense, other federal agencies, and the private sector; (3) potential benefits that the public and private sectors may yield from telemedicine initiatives; and (4) barriers facing telemedicine implementation. Our recommendations are designed to help move federal departments and agencies toward the goals and objectives as stated in the Government Performance and Results Act of 1993.

We are sending copies of this report to the Office of the Vice President; the Secretaries of Defense, Veterans Affairs, Health and Human Services, the Army, the Navy, and the Air Force; the Director, Office of Management and Budget; appropriate congressional committees; and other interested parties. We will provide a copy of this report to the new Ranking Minority Member when named. We will also make copies available to others on request.

This report was prepared under the direction of Mark E. Gebicke, Director, Military Operations and Capabilities Issues, who may be reached at (202) 512-5140 if you or your staff have any questions concerning this report. Other major contributors to this report are listed in appendix VI.

Henry L. Hinton, Jr.
Assistant Comptroller General



Executive Summary

Purpose

During a deployment in the Western Pacific region, a sailor aboard the U.S.S. Abraham Lincoln became seriously injured and was seen and treated by a specialist in San Diego—6,000 miles away. Doctor and patient were linked by telemedicine, which, in its broadest sense, refers to the use of communications technology to help deliver medical care without regard to the distance that separates the participants. In addition to the Department of Defense (DOD), other federal agencies, state governments, and private organizations support telemedicine initiatives.

Congress has raised questions about the federal government's role in advancing telemedicine. In this regard, the Chairman and Ranking Minority Member, Subcommittee on Research and Development, House Committee on National Security, asked GAO to help determine the steps that DOD and the federal government need to take to realize the full potential of telemedicine and achieve cooperation with the private sector. Specifically, this report addresses the (1) scope of public and private telemedicine investments; (2) telemedicine strategies among DOD, other federal agencies, and the private sector; (3) potential benefits that the public and private sectors may gain from telemedicine initiatives; and (4) barriers facing telemedicine implementation.

Background

Depending on how it is defined, telemedicine can involve the use of imaging and diagnostic equipment to gather data from a patient, computer hardware and software to record data, communication lines or satellites to send the data from one location to another, and computer equipment at the receiving end for a physician or specialist to interpret the data. A telemedicine system could be as simple as a computer hookup to a medical reference source or as advanced as robotic surgery. A comprehensive system would integrate various applications—clinical health care delivery, management of medical information, education, and administrative services—within a common infrastructure. This infrastructure includes the physical facilities and equipment used to capture, transmit, store, process, and display voice, data, and images.

Telemedicine has existed in some form for almost 40 years. Early expansion was confined, however, by the cost and limitations of the technology. Recent technological advances, such as fiber optics, satellite communications, and compressed video, have eliminated or minimized many of these problems, fostering a resurgence of private and public sector interest in telemedicine.

GAO's review focused primarily on DOD to meet the needs of the House Subcommittee on Research and Development. To provide a broader perspective, the review also encompassed work at numerous other federal agencies, state governments, and private organizations that support telemedicine initiatives. GAO's overall approach was twofold. First, GAO conducted a broad data collection and analysis effort at numerous organizations. Second, GAO performed a cross-cutting case study of public and private telemedicine projects in one state. Georgia was chosen because it had state, academic, and private sector funding for telemedicine efforts as well as collaboration with DOD on telemedicine projects. GAO also reviewed relevant literature to supplement its analysis.

Results in Brief

Collectively, the public and private sectors have funded hundreds of telemedicine projects that could improve, and perhaps change significantly, how health care is provided in the future. However, the amount of the total investment is unknown. GAO identified nine federal departments and independent agencies that invested at least \$646 million in telemedicine projects from fiscal years 1994 to 1996. DOD is the largest federal investor with \$262 million and considered a leader in developing this technology. State-supported telemedicine initiatives are growing. Estimates of private sector involvement are impossible to quantify because most cost data is proprietary and difficult to separate from health care delivery costs.

Opportunities exist for federal agencies to share lessons learned and exchange technology, but no governmentwide strategy exists to ensure that the maximum benefits are gained from the numerous federal telemedicine efforts. The Joint Working Group on Telemedicine (JWGT), created in 1995 under the Vice President's charge to the Secretary of Health and Human Services (HHS) to report on telemedicine issues, is the first mechanism structured to help coordinate federal programs. However, its efforts to develop a federal inventory—a critical starting point for coordination—have been hampered by definitional issues and inconsistent data. In addition, DOD and other federal departments do not have strategic plans to help guide their telemedicine investments, assess benefits, and foster partnerships. Some federal officials are beginning to recognize the need to develop such strategies.

Telemedicine is an area in which public and private benefits converge. Many anecdotal examples demonstrate how telemedicine could improve access and quality to medical care and reduce health care costs. However,

comprehensive, scientific evaluations have not been completed to demonstrate the cost benefits of telemedicine. The expansion of telemedicine is hampered by legal and regulatory, financial, technical, and cultural barriers facing health care providers. Some barriers, such as multiple state licenses, privacy, and infrastructure costs, are too broad and have implications too far-reaching for any single sector to address.

Telemedicine technology today is not only better than it was decades ago; it is becoming cheaper. Consequently, the questions facing telemedicine today involve not so much whether it can be done but rather where investments should be made and who should make them. The solution lies in the public and private sectors' ability to jointly devise a means to share information and overcome barriers. The goal is to ensure that an affordable telecommunications infrastructure, with interoperable software and hardware, is in place and that the true merits and cost benefits of telemedicine are attained in the most appropriate manner.

Principal Findings

Investments Are Significant, but Total Is Unknown

Over 35 federal organizations within 9 federal departments or independent agencies, 10 state governments, and numerous private sector organizations sponsor hundreds of telemedicine initiatives in over 40 states. The total investment is unknown because telemedicine costs are often embedded within health care delivery costs and private sector data is proprietary. Of the \$646 million that federal agencies invested in telemedicine from fiscal years 1994 to 1996, DOD invested the most—\$262 million—followed by the Departments of Veterans Affairs (VA), HHS, and Commerce, each investing over \$100 million.

Nearly \$105 million, or 40 percent, of DOD's investment is devoted to unique long-term research and development projects for battlefield applications that the Defense Advanced Research Projects Agency (DARPA) has sponsored. The rest of DOD's investment primarily supports peacetime applications at its medical treatment facilities, particularly to improve information management such as digitized radiology or computerized patient tracking systems. Similarly, the other eight federal departments and independent agencies devoted 57 percent of their combined \$384 million investment for information management. A large portion of

this investment also supported clinical health care delivery and infrastructure development in rural or remote areas.

State telemedicine investments have been expanding health care in rural or remote areas. States with the longest track record, such as Georgia, have taken legislative action to support telemedicine and provide direct funding. Georgia has also set a reduced rate across the state for medical communications. Although estimates of the private sector investment in telemedicine have not been quantified, the Koop Institute estimates that the U.S. market was in the billions of dollars for telecommunications infrastructure, computer hardware and software, and biomedical equipment. Many private organizations also use telemedicine to help deliver health care.

No Federal Strategy Exists to Maximize the Value of Telemedicine Investments

No formal mechanism or overall strategy exists to ensure that telemedicine development is fully coordinated among federal agencies to serve a common purpose. Numerous federal, state, and private sector groups are involved in telemedicine activities. The federal agencies involved are seeking solutions to more narrowly defined problems that fall under their purview. For example, DOD has been instrumental in developing telemedicine technologies that could deliver medical care to the battlefield or operations other than war. The National Aeronautics and Space Administration is interested in telemedicine primarily to understand its application to medical care in space. Agencies within HHS are interested in ways to deliver health care to a variety of populations, including those in rural or remote locations.

The technologies that the various agencies are employing or developing for their own missions can be related. For example, federal projects are experimenting with teleradiology—radiologic image transmission within and among health care organizations. These efforts do not necessarily indicate that unwanted duplications are occurring, but they illustrate the potential for one agency to be aware of and take advantage of relevant technologies being developed by another agency.

Although some interagency coordination occurs on an ad hoc or narrow basis (e.g., through working groups, symposiums, technology demonstrations, and joint programs), these efforts do not provide a firm basis for technology exchange. JWGT has tried to fill the information gap and facilitate coordination among federal departments or agencies. Its efforts to develop a comprehensive inventory of federally funded

telemedicine projects have been hampered by several factors, including the lack of a consistent definition and incompatible agency data. JWGT was charged to prepare a report on federal telemedicine projects, the range of potential telemedicine applications, and public and private actions to promote telemedicine and remove existing barriers to its use. In addition, the Telecommunications Act of 1996 (P.L. 104-104) directed the Secretary of Commerce, in consultation with the Secretary of HHS, to submit a report to Congress concerning JWGT activities.¹ Even DOD does not know the full scope of its telemedicine efforts partly because of the lack of agreement over what constitutes telemedicine. Also, DOD-wide oversight is exacerbated because numerous diverse organizations generate projects at low levels.

Without a departmentwide strategy to guide investments, some DOD programs, such as DARPA's unique long-term research and development efforts, may be difficult to justify and therefore may be in jeopardy. Also, organizational structure and oversight responsibilities are still evolving, and a comprehensive budget for the telemedicine program has not been developed. Except for DARPA, DOD has developed only limited partnerships with the private sector. Moreover, DOD's experiences may be indicative of telemedicine activities throughout the federal government. Some federal agencies are beginning to recognize the need to develop a telemedicine strategic plan.

Given the wide range of private sector sponsors of telemedicine (manufacturers, utility companies, managed care organizations, and professional medical groups), it is understandable that no single private sector strategy exists for the advancement of this emerging technology. However, the private sector has acknowledged the need to build public and private partnerships to facilitate telemedicine development.

Telemedicine Benefits Are Promising but Largely Unquantified

By eliminating distance as a factor in medical care, telemedicine has the potential to address some of the access, quality, and cost problems facing public and private health care providers. DOD believes it could reduce battlefield fatalities if a medic were to consult with a more skilled specialist early in the treatment process. The Navy has begun using telemedicine to provide access to medical care for the 100,000 to 150,000 personnel routinely deployed at sea. That access proved critical for one sailor who injured his hand on a gun mount. The injured sailor was

¹The Secretaries of Commerce and HHS issued their final report to Congress and the Vice President on January 31, 1997.

transferred from another ship to the U.S.S. Abraham Lincoln with the gun mount part still implanted in his hand. X-rays and video of his injury were transmitted to San Diego, where a specialist consulted with the ship's surgeon to treat the injury. The sailor returned to light duty on his ship 3 days later. Similarly, emergency medical technicians could treat accident victims more quickly in peacetime by using telemedicine to consult with a physician.

Although a 1992 private sector study estimated that using video conferencing for medical consultations and continuing medical education could reduce health care costs by \$200 million annually, the true merits, limitations, and cost-effectiveness of telemedicine have yet to be empirically quantified. Many anecdotal examples exist to show how telemedicine can save money. For example, teleradiology used on a deployed aircraft carrier eliminated the need for 30 evacuations and saved about \$100,000 over a 4-month period. Over a 2-year period, Texas saved about \$495,000 in transportation costs by using telemedicine to care for its prison inmates rather than transfer them to another facility.

Large infrastructure start-up costs, high operational costs, and inappropriate utilization, however, could offset potential cost savings. Without sharing telecommunication systems with other users, health care facilities may find that their costs per consultation are prohibitively high. In managed health care settings, for example, many costs, including monthly network expenses and physician salaries, are fixed, and potential users must determine if telemedicine technology is economically feasible. In fee-for-service settings, in which physician salaries depend on the services provided, third-party payers, such as Medicare, are concerned that providers may use complex and costly telemedicine technologies when less costly techniques may be sufficient. Officials from HHS' Health Care Financing Administration are concerned that Medicare expenditures could increase significantly if telemedicine consultations are reimbursed. Although various reports have estimated that Medicare expenditures would increase by billions of dollars, Health Care Financing Administration officials could not estimate the amount of the potential increase, preferring to wait until they complete several cost evaluations currently underway.

Literature notes, however, that past telemedicine projects throughout the United States have not included an evaluation component. The limited evaluations that have been performed often did not have a sufficient sample size. Several comprehensive evaluations are currently underway to

address some of these issues, but the results will not be known for several years.

Barriers Currently Inhibit Adoption of Telemedicine

Most experts agree that the major barriers to implementing telemedicine are known but that the solutions are complex and require cooperative efforts by all sectors involved in health care. Legal and regulatory barriers, such as physician licensure and malpractice liability, impede private sector organizations more than they do government providers. Financial barriers, such as reimbursement for certain medical procedures, affect the private sector, whereas the lack of an affordable telecommunications infrastructure impedes all sectors. Some technical barriers, such as interoperability and design standards, may persist even after an infrastructure is established. Physician and patient resistance may pose cultural obstacles.

Partnership efforts are already underway by policymakers and various groups in the public and private sectors to develop strategies and options for overcoming many of the barriers to telemedicine applications. Some groups believe that federal initiatives are needed to resolve more complex legal issues, such as licensure for an interstate practice of telemedicine.

Recommendations

Although there is a need to develop national goals and objectives to guide federal telemedicine investments, it would be difficult for an individual department or agency to be the architect of a governmentwide strategy. JWGT is already performing some interagency coordination associated with carrying out the Vice President's charge to the Secretary of HHS to prepare a comprehensive report on telemedicine issues. Therefore, JWGT is in a good position to expand its work and take the lead in proposing a coordinated federal approach for investing in telemedicine. Such efforts should provide a framework to optimize the value of federal telemedicine investments with activities sponsored by the states and private sector.

Accordingly, GAO recommends that the Vice President direct JWGT, in consultation with the heads of federal departments and agencies that sponsor telemedicine projects, to propose a federal strategy that would establish near- and long-term national goals and objectives to ensure the cost-effective development and use of telemedicine. In addition, the proposed strategy should include approaches and actions needed to

- establish a means to formally exchange information or technology among the federal government, state organizations, and private sector;
- foster collaborative partnerships to take advantage of other investments;
- identify needed technologies that are not being developed by the public or private sector;
- promote interoperable system designs that would enable telemedicine technologies to be compatible, regardless of where they are developed;
- encourage adoption of appropriate standardized medical records and data systems so that information may be exchanged among sectors;
- overcome barriers so that investments can lead to better health care; and
- encourage federal agencies and departments to develop and implement individual strategic plans to support national goals and objectives.

Further, because DOD is the major federal telemedicine investor and manages one of the nation's largest health care systems, it is in a good position to help forge an overall telemedicine strategy. A first step is to develop a departmentwide strategy. Therefore, GAO recommends that the Secretary of Defense develop and submit to Congress by February 14, 1998, an overarching telemedicine research and development and operational strategy. The strategy should

- clearly define the scope of telemedicine in DOD;
- establish DOD-wide goals and objectives and identify actions and appropriate milestones for achieving them;
- prioritize and target near- and long-term investments, especially for goals related to combat casualty care and operations other than war; and
- clarify roles of DOD oversight organizations.

Agency Comments and GAO's Evaluation

GAO provided a draft of this report to DOD, VA, HHS, and the Office of the Vice President. Both DOD and VA concurred with our recommendations. DOD stated that it "... is not alone in finding itself behind the technological bow wave of telemedicine" (see app. III). DOD said that one of its first priorities will be the development of a definition and scope of DOD telemedicine activities. DOD also agreed to establish departmentwide goals and objectives and prioritize investments as part of its strategic telemedicine plan. According to DOD, many pieces of this plan are already in place. VA commented that it would be beneficial for DOD to include VA in its development of an operational strategy for telemedicine activities (see app. IV).

After subsequent discussions with HHS officials regarding agency comments, HHS generally agreed with the concept of our recommendation for JWGT to play a leadership role in proposing national goals and objectives. HHS was concerned that a governmentwide strategy could be overly prescriptive, given the evolving state of telemedicine technology (see app. V). GAO's recommendation was not intended to imply that JWGT direct federal agencies' investments in telemedicine initiatives but rather that JWGT develop a roadmap for federal agencies to use as a guide for their investments. HHS also stated that it might be better to require individual departments to develop their own strategies before an overarching federal strategy is proposed. GAO believes that individual strategies should be developed but that these strategies would not ensure an interagency commitment to national goals and objectives or serve as a guide to prevent duplicative investment efforts. GAO further believes that some agencies, such as DOD and VA, might be in a better position than others to move forward with individual strategies, whereas other agencies would benefit from an overall federal plan to help develop their individual strategies.

Also, GAO recommended that JWGT membership be expanded to include private and state representation. HHS expressed concerns about implementing this portion of the recommendation due to requirements in the Federal Advisory Committee Act. Among other things, the act would require reimbursement of any state and private sector representative to attend the group's bimonthly meetings. As a result, GAO modified its recommendation by deleting suggestions to expand JWGT beyond federal agency membership. GAO believes that the specific vehicle chosen is not important as long as the interaction among the federal, state, and private sectors improves. JWGT should have the flexibility to choose the most effective vehicle for fostering such interaction.

Within the Office of the Vice President, the Chief Domestic Policy Advisor and Senior Director for the National Economic Council did not provide GAO with written comments. The Senior Director for the National Economic Council, however, raised questions regarding the impact of the Federal Advisory Committee Act on expanding JWGT membership to include private and state representation. Further, DOD and HHS provided specific technical clarifications that we incorporated in the report as appropriate.

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Abbreviations

| | |
|-------|---|
| AT&T | American Telephone and Telegraph |
| BOP | Bureau of Prisons |
| DARPA | Defense Advanced Research Projects Agency |
| DOD | Department of Defense |
| FDA | Food and Drug Administration |
| FTCA | Federal Tort Claims Act |
| GAO | General Accounting Office |
| HCFA | Health Care Financing Administration |
| HHS | Department of Health and Human Services |
| IHS | Indian Health Service |
| JWGT | Joint Working Group on Telemedicine |
| MATMO | Medical Advanced Technology Management Office |
| MDIS | Medical Diagnostic Imaging Support |
| MHSS | Military Health Services System |
| NASA | National Aeronautics and Space Administration |
| ORHP | Office of Rural Health Policy |
| VA | Department of Veterans Affairs |

Introduction

The influx of recent advanced communications technologies, coupled with changing incentives in the health care marketplace, has resulted in a resurgence of interest in the potential of telemedicine. This technology is expected to affect health care providers, payers, and consumers in both the public and private sectors. Telemedicine is also expected to impact how medical care is delivered, who delivers it, and who pays for it.

Although many players throughout the federal government and the private sector are involved in telemedicine, the Department of Defense (DOD) is considered a leader in research related to telemedicine efforts. DOD has devised ways to use this new technology to deliver health care on the battlefield or during peacetime operations. Currently, DOD has a major telemedicine effort underway to provide medical support for U.S. peacekeeping forces in Bosnia.

What Is Telemedicine?

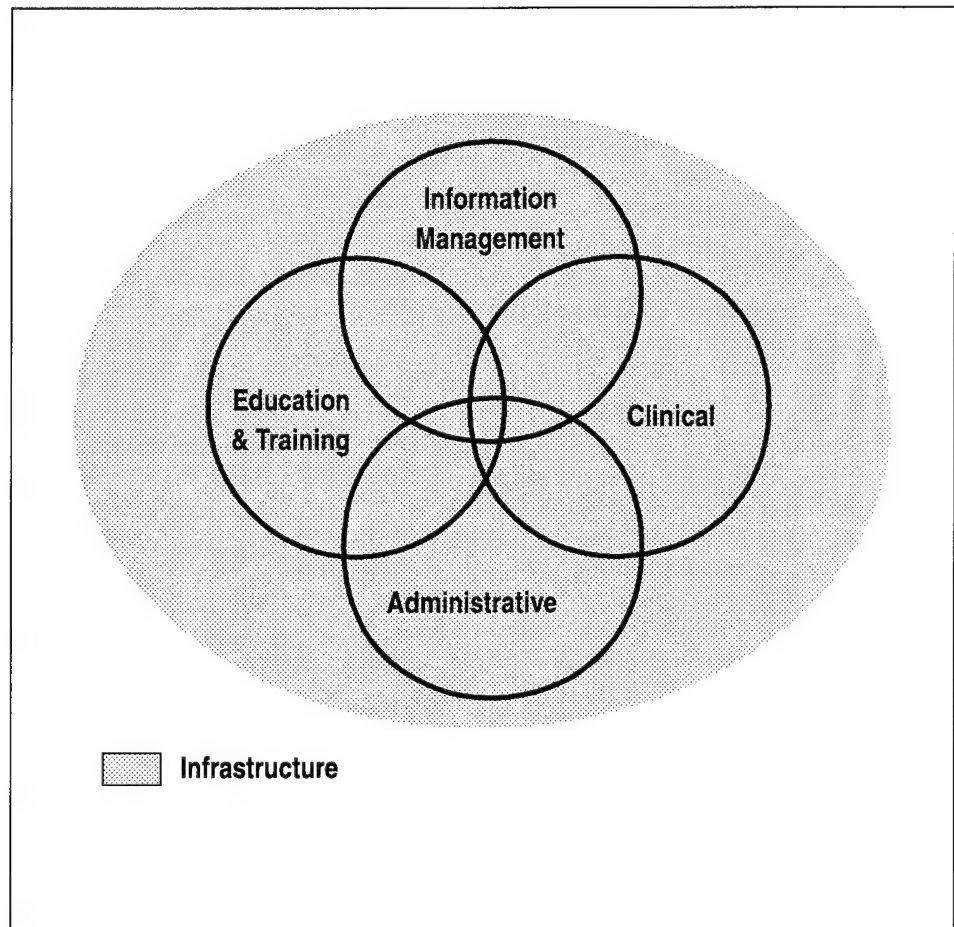
As with other emerging technologies, telemedicine has not been precisely defined. An October 1996 Congressional Research Service report noted that the definition of telemedicine continues to be debated.¹ The problem centers on what to include in the concept. The essence of telemedicine is providing medical information or expertise to patients electronically that would otherwise be unavailable or would require the physical transport of people or information.

Telemedicine can be described in many different ways, depending on the level of technology used, main purpose of its use, and transmission timing. At the lowest level, telemedicine could be the exchange of health or medical information via the telephone or facsimile (fax) machine. At the next level, telemedicine could be the exchange of data and image information on a delayed basis. A third level could involve interactive audio-visual consultations between medical provider and patient using high-resolution monitors, cameras, and electronic stethoscopes. This level is currently receiving much attention in literature and demonstrations.

A more comprehensive telemedicine system would integrate all components of technology for clinical, medical education, medical information management (also called informatics), and administrative services within a common infrastructure. The relationship of these components is shown in figure 1.1.

¹Telemedicine/Telehealth Description and Issues, Congressional Research Service, 1996.

Figure 1.1: Application Components of an Integrated Telemedicine System



History of Telemedicine

Under its broadest definition, telemedicine has been practiced in some form in the United States for almost 40 years. Most projects have demonstrated that this technology can be used to exchange medical information between sites in both rural and urban settings. The first telemedicine project in the United States was established in 1959, when the University of Nebraska transmitted neurological examinations across campus. In 1964, the university established a telemedicine link with a state mental hospital 112 miles away. The National Aeronautics and Space Administration (NASA) was a telemedicine pioneer in the 1960s with its satellite support of a telemedicine project, conducted by the National Library of Medicine, that provided health services to the Appalachian and Rocky Mountain regions and Alaska. In the 1970s, NASA also sponsored a project, implemented with the Indian Health Service and the Department of Health, Education, and Welfare, on an Indian reservation in Arizona.

According to a report issued by the Institute of Medicine, only one telemedicine project that started before 1986 has survived.² Evaluations of these projects indicated that the equipment was reasonably effective and users were satisfied. However, when external funding sources were withdrawn, the programs could not be sustained, indicating that the high cost of complex, technically immature systems was a problem.

Congressional and Executive Interest in Telemedicine

In 1993, several members of Congress established the Senate and House Ad Hoc Steering Committee on Telemedicine to advise legislators on integrating new technologies into health care reform strategies. In 1994, the House Committees on Veterans Affairs and Science, Space, and Technology held hearings to examine economic and legal barriers that threatened to inhibit the expansion of telemedicine.

In March 1995, the Vice President directed the Secretary of Health and Human Services (HHS) to lead efforts to develop federal policies that foster cost-effective health applications using communications technologies, including telemedicine. HHS was required to prepare a report on current telemedicine projects, the range of potential telemedicine applications, and public and private actions to promote telemedicine and remove existing barriers to its use. The Vice President also directed that this effort include representatives from several specific departments and agencies. As a result, HHS organized the Joint Working Group on Telemedicine (JWGT).³ DOD is providing the funding to carry out JWGT's taskings related to constructing a telemedicine database. In addition, other agencies are providing personnel support. HHS issued a status report on JWGT's efforts to the Vice President in March 1996.

In 1996, the Senate and House Ad Hoc Steering Committee on Telemedicine sponsored a series of discussions by government and private organizations on telemedicine issues, such as financing, malpractice, and clinical standards. Also, the Telecommunications Act of 1996 (P.L. 104-104) directed the Secretary of Commerce, in consultation with the Secretary of HHS, to submit a report to Congress by January 1997 concerning the activities of JWGT regarding patient safety; the efficacy and

²Telemedicine: A Guide to Assessing Telecommunications in Health Care, Institute of Medicine, 1996.

³In addition to HHS, federal departments or agencies represented in JWGT include DOD, Veterans Affairs, Commerce, and Agriculture; NASA; the Federal Communications Commission; and the Office of Management and Budget. In addition to federal participation, JWGT also contacts private sector representatives involved in telemedicine to gain consensus on key issues. Among these groups are the American Medical Association, the Physicians Insurers Association of America, Arent Fox, RAND, the American College of Nurse Practitioners, and the American Nurses Association.

quality of the services provided; and other legal, medical, and economic issues related to the utilization of advanced telecommunications services for medical purposes. The Secretaries of Commerce and HHS plan to jointly issue a final report to Congress and the Vice President on January 31, 1997.⁴

The Telecommunications Act of 1996 also directed the Federal Communications Commission to explore actions that would provide basic telecommunications services to all rural users. The act further required telecommunications companies to provide discounts to health care providers in rural areas.

Objectives, Scope, and Methodology

As a result of congressional concerns about the federal government's role in advancing telemedicine, the Chairman and Ranking Minority Member, Subcommittee on Research and Development, House National Security Committee, asked us to help determine the steps that DOD and the federal government need to take to realize the full potential of telemedicine and achieve cooperation with the private sector. Specifically, this report addresses the (1) scope of public and private telemedicine investments; (2) telemedicine strategies among DOD, other federal agencies, and the private sector; (3) potential benefits that the public and private sectors may yield from telemedicine initiatives; and (4) barriers facing telemedicine implementation.

Our overall approach was twofold. First, we conducted a broad data collection and analysis effort across nine federal departments and agencies and selected private sector entities. Second, we performed a cross-cutting case study of DOD, other public agencies, and private telemedicine projects in Georgia that provided us with examples for each objective. We chose Georgia because it had state, academic, and private sector funding for telemedicine efforts as well as collaboration with DOD on telemedicine projects. We used a comprehensive definition of telemedicine that included all four applications of telemedicine linked together within a common infrastructure. We excluded the lowest level of this technology—telephones and fax machines—from our data collection efforts.

To determine what role DOD and other federal agencies played in the development of telemedicine, we collected and analyzed data on ongoing federal projects and applicable funding levels for fiscal years 1994-96. We

⁴The final report to Congress and the Vice President has been issued.

also interviewed officials within numerous DOD components and eight federal departments and agencies. In addition, we reviewed DOD Inspector General reports, conference reports, and relevant information available through the Internet.

To determine the efforts of the public and private sectors to advance telemedicine technology, we compared federal projects and funding levels and efforts to identify redundancy among projects. We categorized federal projects by one of the components of telemedicine identified through our analysis of definitions. We reviewed relevant literature on state and private sector efforts. We held discussions with state and private sector representatives involved with telemedicine projects. In addition, we attended bimonthly JWGT meetings to keep abreast of its ongoing efforts.

To obtain an overview of state programs, we interviewed state officials and users from Georgia, North Carolina, and Texas who were involved in their state's telemedicine network. We also interviewed officials of the Western Governors Association and George Washington University on their recent study on state initiatives.

To identify information on private sector involvement in telemedicine, we interviewed officials and obtained data from many national associations and organizations. We also talked with representatives from private sector health care facilities in Georgia and Minnesota and equipment and telecommunications companies in Georgia and the Washington, D.C., area.

To determine the potential benefits of and barriers facing telemedicine, we interviewed officials involved with telemedicine in DOD, other federal and state agencies, and the private sector. Also, we analyzed telemedicine evaluations and studies of potential barriers. We did not validate potential cost savings data. Appendix I contains a comprehensive listing of all of the federal, state, and private organizations we visited.

We conducted our work from January to December 1996 in accordance with generally accepted government auditing standards.

Many Entities Are Involved in Telemedicine, but the Total Investment Is Unknown

Numerous federal, state, and private organizations are sponsoring hundreds of telemedicine initiatives, but the total investment is unknown. Even though the federal government's total investment cannot be determined, we identified nine federal departments and independent agencies that invested a minimum of \$646 million in telemedicine initiatives for fiscal years 1994-96. During that time, DOD invested the most, \$262 million, followed by the Departments of Veterans Affairs (VA), HHS, and Commerce, each investing over \$100 million. The focus of the investments varied depending on the agency's mission, but most projects were directed toward medical information systems, such as computerized patient records or digitized imagery. Other projects were directed toward infrastructure development, clinical applications for rural or remote areas, and medical education and training. The Defense Advanced Research Projects Agency (DARPA), working with some academic and private sector entities, is doing unique near- and long-term research for battlefield applications.

Over 40 states have some type of telemedicine initiative underway funded by federal agencies, the private sector, or the states themselves. Ten of these states, especially Georgia and Texas, have taken an active role in sponsoring telemedicine initiatives. Estimates of telemedicine and related technology investments in the private sector have not been quantified because telemedicine costs are difficult to separate from health care delivery costs and most cost data is proprietary. Most private sector organizations, including telecommunication companies, private hospitals, and managed care organizations, have focused their telemedicine efforts on the telecommunications infrastructure. Other private sector efforts include developing the computer and medical equipment needed for telemedicine applications and delivering health care directly via telemedicine.

Federal Investment Is Significant but Difficult to Determine

Estimating total costs for telemedicine is difficult because agencies that deliver health care, such as VA, embed telemedicine costs within their health care programs. Also, the lack of a consistent definition of telemedicine may result in an agency not including certain project costs, whereas another agency would include the same type of projects in its costs.

We identified over 35 federal organizations within 9 departments and independent agencies that were investing in telemedicine projects. Most officials from these departments did not know the amount their

departments had invested in telemedicine. However, as table 2.1 shows, the federal government invested at least \$646 million for fiscal years 1994-96. Details of federal telemedicine projects appear in appendix II.

Table 2.1: Telemedicine Investments by Nine Federal Departments and Independent Agencies, Fiscal Years 1994-96

Dollars in millions

| Department or agency | FY 94 | FY 95 | FY 96 | Total |
|---------------------------------|----------------|----------------|----------------|----------------|
| DOD | \$37.1 | \$106.5 | \$118.3 | \$261.9 |
| VA | 45.1 | 56.6 | 40.2 | 142.0 |
| HHS | 39.5 | 14.6 | 55.8 | 109.9 |
| Commerce | 56.1 | 46.2 | 3.6 | 106.0 |
| NASA | 1.0 | 3.3 | 2.3 | 6.6 |
| Agriculture | 2.9 | 3.0 | 3.5 | 9.3 |
| Justice | 0 | 0 | 3.2 | 3.2 |
| National Science Foundation | 1.6 | 3.3 | 1.9 | 6.8 |
| Appalachian Regional Commission | 0.3 | 0 | 0 | 0.3 |
| Total | \$183.5 | \$233.6 | \$228.8 | \$646.0 |

Note: Figures do not add due to rounding.

Source: Our analysis of data from various sources within the federal departments and agencies.

Although some agencies have attempted to develop an inventory of federal telemedicine projects, a governmentwide inventory has not been completed. For example, NASA had contracted with the Center for Public Service Communications in 1993 to develop an inventory of public and private telemedicine initiatives. Funding was cut in 1994, and the inventory subsequently became outdated. In 1995, the DOD Inspector General developed a directory of DOD telemedicine demonstrations and projects. According to the DOD Inspector General, this effort represented a starting point to track DOD's telemedicine initiatives. JWGT expected to complete a federal inventory in January 1997.

DOD Invests in Battlefield and Peacetime Applications

DOD and each of the military services have collectively invested more in telemedicine initiatives than any other federal department or agency. However, DOD and the services have not established telemedicine budgets. They currently initiate projects by reprogramming funds from other programs and are developing budget estimates for fiscal years 1998-2003.

Nearly half of DOD's \$262 million telemedicine investment was devoted to unique long-term research and development of battlefield applications of

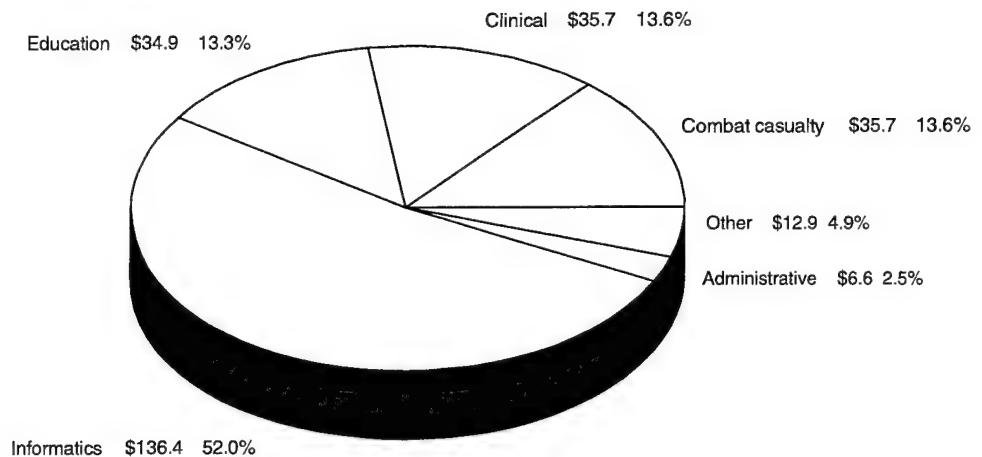
telemedicine. For example, DARPA is developing devices to treat wounded soldiers, such as a hand-held, physiologic monitor that will help a combat medic locate a wounded soldier and monitor the soldier's vital signs. The Army is investing in the development of a "virtual reality" helmet that will allow combat medics to consult with a physician during the first critical hour, referred to as the golden hour by DOD, after a soldier is wounded. The Navy has directed most of its telemedicine investments to establish telecommunications connectivity between its deployed ships and U.S.-based medical centers.

The remaining DOD investment focused on peacetime health care. The Army, for example, is building medical communications networks to link its medical centers with each other. These networks will support numerous medical functions, particularly digitized, filmless x-rays or teleradiology. The most significant Air Force telemedicine effort will establish communications links between several Army, Navy, and Air Force medical centers, hospitals, and clinics in TRICARE Region 6.¹

DOD's investment helps provide medical care in several functional applications within a telemedicine system, including clinical health care delivery, medical information management, education, and administration. Figure 2.1 shows DOD's investment according to functional application.

¹TRICARE is a DOD health care delivery plan that requires the Army, the Navy, and the Air Force medical systems to pool resources to provide quality health care that is accessible and affordable. The plan has 12 regions. Region 6 supports Oklahoma, Arkansas, and major portions of Louisiana and Texas. Within this 4-state region, 19 military health care facilities support nearly 1 million beneficiaries.

**Figure 2.1: Distribution of DOD's
 Telemedicine Investment by
 Functional Application**



Note: Dollars are in millions.

Source: Various organizations within DOD.

DOD's Investment Could Increase Significantly

DOD's investment in telemedicine could double or even triple by the year 2003 depending on key budget decisions to be made in fiscal year 1997. Each service is currently developing its program objective memorandum for fiscal years 1998-2003. With regard to telemedicine, the services estimate that \$464 million will be needed for the Theater Medical Information Program. This program is designed to link all the medical information systems within a battlefield or operational theater, including medical command and control, medical logistics, medical intelligence, blood management, and aeromedical evacuation. Such information will be used to collect and analyze environmental health data, and the analysis will help battlefield commanders make tactical decisions that may reduce disease and non-battle-related injuries.

The current deployment of telemedicine to Bosnia, known as Primetime III, is an early test of some of the Theater Medical Information Program's information management concepts. For example, Primetime III will use telemedicine to provide medical units access to numerous medical capabilities at any time during the day or night. These capabilities include computerized medical records; full-motion remote video consultation between theater medical units and tertiary care facilities; far forward delivery of laboratory and radiological results and prescriptions; digital

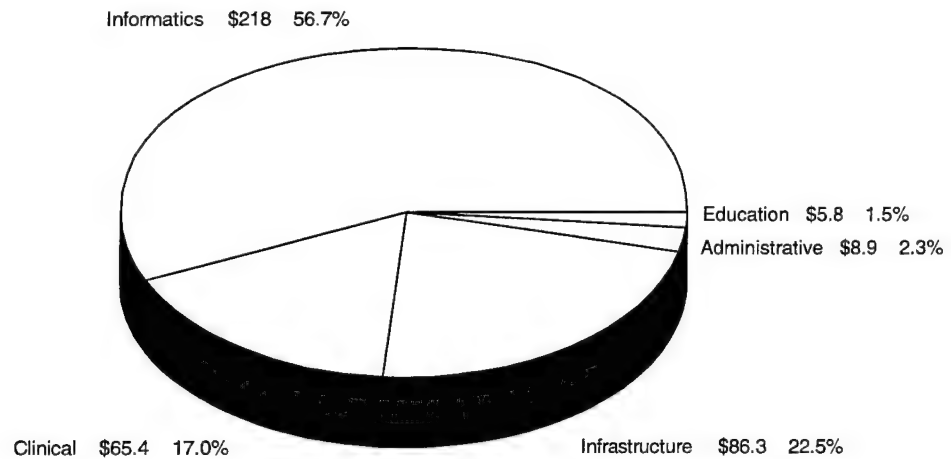
diagnostic devices, such as ultrasound and filmless teleradiology; and medical command and control technologies.

To achieve this access, DOD established an integrated electronic network between (1) the Landstuhl Regional Medical Center in Germany, (2) field hospitals in Hungary and Bosnia, (3) smaller brigade operating base medical units and forward operating base medical support units in Bosnia, (4) the U.S.S. George Washington in the Adriatic Sea, and (5) nine DOD medical centers located within the continental United States and Hawaii. To date, Primetime III expenditures totaled \$14.6 million—the Office of the Assistant Secretary of Defense for Health Affairs funded \$12.4 million, and Army's 5th Corps in Europe funded \$2.2 million. Total costs are estimated to be \$30 million.

Other Federal Agencies Invest in a Range of Telemedicine Activities

Eight civilian federal departments or independent agencies with various roles in providing or supporting health care delivery invested \$384 million in telemedicine from fiscal years 1994 to 1996. In some cases, these investments represented the estimated total costs of projects for the year first awarded and not the costs agencies actually incurred during those years. Most expenditures provided clinical services, telecommunications infrastructure, and information management resources, as shown in figure 2.2. In many instances, the agencies' investments were directed toward rural populations or focused on teleradiology.

Figure 2.2: Distribution of Non-DOD
Federal Investments by Telemedicine
System Application



Note: Dollars are in millions.

Source: Various sources within the eight federal departments and independent agencies.

State Investments Are Growing but Are Not Quantified

In May 1995, the Primary Care Resource Center at George Washington University completed a comprehensive review and analysis of the states' telemedicine activities. The report, entitled State Initiatives to Promote Telemedicine, explores the role that states have played in telemedicine and identifies their various initiatives, but it does not quantify total investments.

The study found that overall state involvement in telemedicine has been expanding, particularly to provide health care to rural or remote areas. Although over 40 states have some initiatives underway that are funded by federal agencies, the private sector, or the states themselves, 10 actively sponsor telemedicine initiatives. Some states focus on the high costs of providing a telecommunications infrastructure by requiring carriers to subsidize services to certain educational and health care institutions, particularly in rural or remote areas.

We reported in 1996 that three states—Iowa, Nebraska, and North Carolina—worked with the private sector and potential users to encourage private investment and ensure the availability of services in less densely populated areas.² These states encouraged private investments in

²Telecommunications: Initiatives Taken by Three States to Promote Increased Access and Investment (GAO/RCED-96-68, Mar. 12, 1996).

advanced telecommunications infrastructure by offering to become major customers of these services from the telephone companies. As a result of the states' efforts, the telephone companies made improvements faster than they would have on their own.

Two states—Georgia and Texas—have well-established telemedicine programs. Georgia developed a statewide telemedicine network and passed legislation to support telemedicine. Texas owns and operates some statewide networks and regulates the installation and costs of its telecommunications infrastructure to support telemedicine. Another state—North Carolina—provides funding to a university that is performing telemedicine consultations to the largest prison in North Carolina and two rural hospitals

Georgia

Georgia's telemedicine program began when the governor signed the Georgia Distance Learning and Telemedicine Act of 1992, which established a telecommunications network to ensure that all residents of Georgia have access to quality education and health care. The act allowed the Public Service Commission to set a special flat-rate structure across the state and allowed one communications company to cross other companies' service areas to set up a statewide infrastructure.

The program received about \$70 million from the state's Economic Development Fund, which was established using fines paid by a telecommunications company. As of February 1996, approximately \$9 million had been allocated for the telemedicine portion of the network, and the remaining \$60 million was spent on distance education using telecommunications. The telemedicine money funded the network infrastructure, equipment for the sites, one-half of the monthly line charges for the first 2 years of operations, and one-half of the maintenance costs per site in the second year. The sites pay for personnel, administration costs, and remaining line charges. In addition, the state's Department of Human Resources provides approximately \$350,000 annually to advance telemedicine in rural communities.

The Georgia telemedicine network includes 60 sites serving 159 counties. Seven of the sites are state correctional facilities. Three of these facilities have permanent telemedicine systems, with the other four serviced by a mobile telemedicine van. The network is primarily used to provide inmates with more timely access to specialty care. Before telemedicine, non-emergency specialty care services took 30 to 90 days to schedule.

With the implementation of the system, inmates can see a specialist in 7 to 21 days.

Several Georgia departments and agencies are actively involved in the statewide network. A governing board sets policies and awards funding for the network. The state's Department of Administrative Services develops and administers the infrastructure network. The Medical College of Georgia plans, coordinates, and implements the daily operations of the network's medical system, and the Office of Rural Health and Primary Care, within the Department of Human Resources, approves proposed expenditures, ensuring that funding is used entirely to advance telemedicine in rural communities.

Texas

Texas uses state-operated networks to provide telemedicine consultations and continuing medical education to small rural clinics. For example, the University of Texas Health Science Center at San Antonio operates the South Texas Distance Learning and Telehealth infrastructure network. In addition, the Texas Tech Health Sciences Center and the University of Texas Medical Branch at Galveston provide all of the medical care to the 130,000 inmates at 104 state prison facilities. These facilities have physicians and other clinical staff to provide primary care, but patients who require specialized care are referred to the Galveston and Texas Tech hospitals. The state has funded a telemedicine project to link specialists in Galveston with four state prisons and has plans to expand the project to other locations. Texas officials estimated that telemedicine has greatly reduced the number of patients transferred from their home facilities to the hospitals.

The state has arranged with the private owners of the telecommunications systems to charge a flat rate for usage. Specifically, rural clients and other low utilization users are charged \$425 per month for up to 40 hours of usage. Commercially, a facility would pay an access charge of \$475 plus a use charge of \$60 to \$100 per hour.

North Carolina

In 1992, the East Carolina University Medical School began providing telemedicine consultations to the state prison in Raleigh, 100 miles away. Physicians see and talk to the patients via the telemedicine link and then diagnose and prescribe medications when necessary. A digital stethoscope, graphics camera, and miniature hand-held dermatology camera are used to aid patient examinations. These tools, along with a

computerized patient record system and a comprehensive scheduling system, form the basis of an integrated health care information system being implemented across a wide area network in North Carolina. The model developed for the prison system is now being expanded to six rural hospitals within the state and the naval hospital at Camp Lejeune.

Private Sector Is Investing Mostly in Infrastructure

Estimates of private sector investments have not been quantified because telemedicine costs are difficult to separate from health care delivery costs and most cost data is proprietary. The Koop Institute estimates that the U.S. telemedicine market totals \$20 billion for telecommunications infrastructure, computer hardware and software, and biomedical equipment. A breakdown of this funding is unavailable. Further, any estimate of private sector investments would partially duplicate amounts reported by the public sector because of contract and grant relationships. Also, the Koop Foundation, a sister organization to the institute, is expected to compile an inventory by the year 2000 of private sector telemedicine projects.³

Dozens of private interests, including telecommunications companies, equipment manufacturers, private hospitals, and managed care organizations, have positioned themselves to capture future telemedicine market shares. For example, telecommunications companies are providing the infrastructure that allows telemedicine consultations and data transfers to occur. Private companies built and own the National Information Infrastructure and lease the lines to telemedicine users and others.⁴ Most telemedicine end users do not own high-technology telecommunications lines and thus rely on private enterprise to provide this infrastructure.

Equipment manufacturers use their own funds and federal financial support to develop data transmission technologies, such as digital coding and decoding equipment, to facilitate telemedicine consultations. Private firms also develop medical sensory devices, such as electronic stethoscopes, specialized cameras, and robotic surgical assistance devices.

³Former Surgeon General C. Everett Koop, in response to requests from the White House and private sector, formed a health informatics initiative to foster and facilitate public and private sector leadership in the health component of national and global information infrastructures.

⁴The National Information Infrastructure consists of a physical system of telecommunications pathways and connections that transmit and receive voice, video, and data. The administration's goal for the infrastructure is to interconnect industry, government, research, education, and each home with advanced telecommunications networks and information resources.

Until recently, most telemedicine efforts in the health care delivery area either received some federal or state funds or were limited to teleradiology. Some providers have now invested in their own telemedicine networks, seeking to achieve cost and operational efficiencies. For example, a large managed care organization in Minnesota established telemedicine networks between its facilities to expand specialty care to members in rural areas. Another provider established telemedicine links among its three facilities in Minnesota, Florida, and Arizona and became one of several health care providers seeking to expand to international telemedicine linkages.

One manufacturer of medical robotics, Computer Motion, Inc., believes that improved automation has been fundamental in opening huge new markets. For example, many surgeons, nurses, and medical assistants all see the use of robotics for laparoscopic surgery as extremely positive. The movements of the laparoscope are smooth, and the video image remains steady throughout the procedure. The physician who, in August 1993, performed the first laparoscopic surgery using the robotic arm said the biggest advantage is that surgeons have complete control and do not have the difficult task of communicating to assistants where to move the laparoscope. Literature indicates that giving directional instructions can be a distraction from the procedure itself; most surgeons can be more efficient if they do not have to keep asking someone to correct the positioning of the scope.

The manufacturing company has been working closely with Yale University in support of research and education programs in telesurgery and robotically assisted laparoscopy. One university official said that the partnership would allow the university to bring robotics into the education system and demonstrate how it could be used effectively to reduce costs and improve the quality of patient care.

Medical robotics continues its rapid expansion into the worldwide marketplace. European countries and various training centers have begun to launch collaborative efforts in medical robotics education. According to the manufacturer, more than 100 robotic arms have been used in approximately 13,000 minimally invasive surgical procedures. Voice control will be a feature of the next generation of robotic arms, which will require clearance by the Food and Drug Administration (FDA).

Federal Government Does Not Have a Strategy to Maximize Value of Telemedicine Investments

No overarching, governmentwide strategy exists to ensure that the most is gained from numerous federal telemedicine efforts. Until recently, there was little or no coordination of telemedicine activities among federal agencies. Although JWGT is a first step toward providing a mechanism to help coordinate federal support of telemedicine, federal departments have not developed agencywide strategies to manage their own telemedicine efforts. Without clear goals and priorities for telemedicine investments, some programs are difficult to justify and may be in jeopardy.

Federal agencies have recognized the need for a strategic plan to fulfill their telemedicine visions. Even as the largest single federal investor and perhaps the main sponsor of long-term telemedicine research, DOD does not have a plan to ensure it is maximizing the value of its investments. As a result, DOD's (1) organizational structure to ensure the infusion of telemedicine into application is still evolving, (2) telemedicine program has not been precisely defined, (3) budgets do not reflect a comprehensive telemedicine program, and (4) partnerships with the private sector have not been fully explored. DOD's telemedicine experiences may be indicative of telemedicine activities throughout the federal government. In addition, the private sector has recognized that telemedicine technologies have developed to the point at which telemedicine strategies are needed to guide investments.

Overall Federal Telemedicine Effort Is Not Well Coordinated

No formal mechanism or strategic plan exists to ensure that telemedicine development is fully coordinated among federal agencies and that telemedicine efforts have a common purpose. A well-coordinated plan is important because over 35 federal government organizations directly or indirectly conduct or sponsor (1) research and development; (2) demonstrations using telemedicine for health care delivery; or (3) evaluations of telemedicine's effects on the quality, accessibility, cost, and acceptability of health care. Some of the involved federal organizations are shown in table 3.1.

Chapter 3
Federal Government Does Not Have a
Strategy to Maximize Value of Telemedicine
Investments

Table 3.1: Federal Organizations Involved in Telemedicine Initiatives

| Organization | Conducts or sponsors | | |
|---|--------------------------|----------------------|-------------|
| | Research and development | Health care delivery | Evaluations |
| Office of the Secretary of Defense for Health Affairs (DOD) | X | X | X |
| DARPA (DOD) | X | | |
| Medical Research and Materiel Command/Medical Advanced Technology Management Office (DOD) | X | X | X |
| Offices of the Surgeons General (DOD) | | X | X |
| Army Medical Command (DOD) | | X | X |
| Military hospitals (DOD) | | X | X |
| Armed Forces Institute of Pathology (DOD) | | X | |
| U.S. Transportation Command (DOD) | | X | |
| Veterans Health Administration (VA) | | X | X |
| Rural Utilities Service (Agriculture) | | X | |
| National Telecommunications and Information Administration (Commerce) | X | | |
| National Institute of Standards and Technology (Commerce) | X | | |
| FDA (HHS) | | | X |
| Health Care Financing Administration (HHS) | | X | X |
| Agency for Health Care Policy and Research (HHS) | X | | X |
| Indian Health Service (HHS) | | X | |
| National Library of Medicine (HHS) | X | | X |
| Office of Rural Health Policy (HHS) | | X | X |
| Bureau of Prisons (Justice) | | X | |
| NASA | X | X | |
| National Science Foundation | X | | |
| Appalachian Regional Commission | | X | |

The organizations involved with telemedicine initiatives are seeking solutions to narrowly defined problems that fall under their purview. For example, the Department of Justice, specifically the Federal Bureau of Prisons (BOP), is responsible for the detention and care of approximately 95,000 prisoners, nearly 4,000 of whom receive medical attention on any given day. A small but growing percentage of these prisoners must currently be moved under guard from detention sites to distant medical facilities for diagnosis and treatment. BOP is interested in telemedicine because of the opportunity to reduce the significant cost of providing medical care to prisoners. In addition, telemedicine offers the chance to reduce the number of times prisoners are taken to outside medical

facilities, thus reducing the potential for escape and risk to the attending medical staff and citizens within the local communities.

Other organizations are using telemedicine to meet their mission needs. For example, NASA is interested in telemedicine primarily to understand its application to medical care in space for future long-duration platforms, such as a space station, and minimize the risk of inadequate medical care for astronauts, which would increase the probability of mission success. The Department of Commerce has two core programs that promote private sector development of advanced telecommunications and information technologies for health-related projects. Within the Department of Agriculture, the Rural Utilities Service plays a key role in the rural aspect of the National Information Infrastructure. One grant awarded in 1996 will help the Rural Utah Telemedicine Associates to implement a mobile health clinic that will provide primary care and specialty consultation via telemedicine technology to rural communities with few or no health care providers.

Some interagency coordination occurs on an ad hoc or narrow basis (e.g., through symposiums, technology demonstrations, and joint programs), but this approach does not necessarily provide a firm basis for technology exchange. Many agency officials we met with cited the lack of an established coordination mechanism as an obstacle to determining information that could help advance telemedicine. Further, some agency officials were concerned about possible redundant efforts, especially those related to teleradiology—the most common current application of telemedicine supported by federal funds. However, the officials lacked information to determine whether the work was redundant or actually complemented other's efforts. Several agency officials said that some federal telemedicine efforts repeated previous mistakes rather than benefited from them because information on previous efforts was not available.

To help fill the information gap, DOD funded JWGT's project to develop a database of all federally funded telemedicine projects. JWGT considers such an inventory a critical first step toward achieving coordination across federal agencies. The database should allow federal agencies to more easily learn about the federal investment in various telemedicine projects. JWGT will make this database available to the public on the Internet to assist states and communities with their own telemedicine plans.

Because of the magnitude of the federal government's involvement in telemedicine development, JWGT has thus far been unable to develop an accurate, comprehensive inventory of federal projects. JWGT believes that its efforts to develop an inventory have demonstrated the weaknesses in the information maintained by federal agencies and highlighted the need for greater attention to routine data collection on federally funded programs. For example, departments or agencies have many different definitions of telemedicine, making it difficult to collect compatible data. The inventory, originally scheduled for release in June 1996, was expected to be released by the end of January 1997. JWGT stated that each participating agency would be responsible for maintaining the inventory. However, members of JWGT have expressed concern as to whether each of the agencies would be supportive of maintaining their inventories.

In addition, JWGT meets approximately twice a month to help coordinate federal telemedicine activities and share relevant information. JWGT meetings include over 60 individuals representing executive branch agencies. However, no representatives from each service's Surgeon General's office or DARPA attend these meetings. Further, private sector participation was limited mostly to professional medical associations.

Federal Agencies Recognize the Need for Department Strategies

In addition to the lack of an overall federal telemedicine strategy, federal agencies do not have departmentwide strategies to maximize the value of their telemedicine investments. If each agency involved in telemedicine had its own strategy, a governmentwide strategy could be built from it. The absence of departmentwide strategies has contributed to unclear definitions of telemedicine and the lack of a comprehensive inventory of telemedicine projects among all involved federal agencies. DOD, as well as other federal agencies, are beginning to recognize that an intra-agency strategy may be the first step to target their investments in telemedicine.

DOD

According to the Assistant Secretary of Defense for Health Affairs, who oversees the Military Health Services System (MHSS), telemedicine will be a major enabling technology in reengineering health care delivery in DOD and throughout the United States.¹ The Assistant Secretary believes that a mature telemedicine infrastructure can reduce health care delivery costs,

¹MHSS is one of the nation's largest health care systems, offering health benefits to about 8.3 million people and costing over \$15 billion annually. The primary mission of MHSS is to maintain the health of military personnel so they can carry out their military missions and be prepared to deliver health care during a time of war. MHSS can also provide health care services in DOD medical treatment facilities to dependents of active duty servicemembers and retirees and their dependents.

but mechanisms must be put in place to manage the infusion of telemedicine into application while still proceeding with appropriate research and development or prototype efforts. However, no such mechanisms are currently in place in DOD.

DOD has recognized the need for a strategic plan to fulfill its telemedicine vision, as stated in the December 1994 testbed plan published by the U.S. Army Medical Research and Materiel Command. This document also stated that the Telemedicine Technology Integrating Committee, led by the Commanding General of the Medical Research and Materiel Command, would develop a plan that would provide a framework for multispecialty integration of entrepreneurial efforts and ensure the optimum use of scarce resources for DOD's peacetime and wartime medical activities. However, no milestones were established for accomplishing this plan.

Health Affairs officials told us that they are responsible for developing an overall strategic plan for telemedicine. As of December 1996, the Assistant Secretary of Defense for Health Affairs had not approved this plan. Officials told us that the DOD telemedicine organizational structure resulting from this plan would be modeled after the one established for DOD's information management and information technology systems. However, no other details were available.

Some defense organizations have begun developing their own strategic plan. For example, in June 1996, the Center for Total Access, which includes TRICARE Region 3 and the Army's Southeast Regional Medical Command, published a 5-year strategic plan to support both commands.² The plan recognizes the need for telemedicine projects to adhere to specific guidelines and provides a framework for ensuring that the projects and initiatives undertaken conform to an open standards environment and that new telemedicine initiatives can easily be integrated with existing systems. However, this regional telemedicine plan could be fundamentally different than the strategic plans of the other 11 TRICARE regions.

Many officials expressed concern as to how telemedicine would be integrated into the continuum of DOD medical care—from the battlefields overseas to the medical treatment facilities in the United States—with so many activities underway and no overriding strategy to link them together.

²Region 3 supports South Carolina, Eastern Florida, and Georgia. It contains 14 triservice medical treatment facilities and provides benefits to over 1 million beneficiaries. The Southeast Regional Medical Command consists of the same states plus Alabama, Kentucky, Mississippi, and Tennessee and an additional four medical treatment centers.

For example, the Army Medical Department must provide mobile, flexible support for its own forces across long distances in a variety of wartime environments. The Army has developed a mission needs statement for medical communications in combat casualty care and established a program manager under an Army program executive office for this work. The Air Force's medical forces are responsible for most of the air evacuations from the theater of operations to the United States in wartime, but the Air Force is not part of the Army's medical communications initiative. Army officials acknowledged that this initiative should eventually be a triservice program. Further, no parallel mission needs statement ensures the continuum of care from theater to the continental United States.

Without a formal strategy to define the goals and objectives of DOD's telemedicine initiatives, some DOD programs may be difficult to justify and therefore may be in jeopardy. For example, research and development efforts led by DARPA are subject to discontinuation due to a change in the agency administrator's priorities. DARPA initiated its telemedicine efforts in fiscal year 1994 with a defined program to find ways to improve medical care on the battlefield. Even though DARPA's efforts are starting to mature, there is no clear plan regarding how individual projects will be infused into application. DARPA will be looking to the individual services to continue its research and development function.

Other Federal Agencies

NASA, a pioneer in developing telemedicine technologies for almost 40 years, is developing a strategic plan for its telemedicine initiatives. The plan will address the use of telemedicine in the human space flight program and the use of NASA-developed technology in telecommunications, computers, and sensors to enhance health care delivery for humans in space. The plan will also incorporate industry input into these areas.

According to 1994 VA testimony, the use of telemedicine is having a major impact on VA's approach to health care, but VA does not have a telemedicine strategic plan. To provide overall leadership to its telemedicine program, VA recently established the position of Chief of Telemedicine. This official serves as the principal advisor on telemedicine to the Offices of the Under Secretary for Health, Patient Care Services, and Chief Information Officer. VA officials told us that the Chief of Telemedicine would develop a strategic plan. Other responsibilities of the Chief include facilitating the coordination of VA facilities undertaking telemedicine projects; overseeing VA activities regarding selection,

funding, and evaluation of telemedicine projects; consulting with medical centers about the application of telemedicine standards; and identifying needs for telecommunications and infrastructure support.

HHS does not have a strategic plan linking the efforts of its six agencies investing in telemedicine. HHS officials believe that JWGT effectively communicates information about telemedicine development to the six applicable HHS agencies. However, agency officials acknowledged that a strategic plan may be needed. The officials also stated that such a plan should strengthen, support, and build on the work of JWGT and not create a new bureaucracy.

DOD's Telemedicine Efforts Are Diffused and Weakly Linked

Although DOD has a large and growing investment in telemedicine, it has not yet structured its telemedicine initiatives, which are led by numerous organizations, to determine if, collectively, their cost is commensurate with potential benefits DOD stands to gain. Within DOD (1) the roles of numerous key players are still evolving, (2) the telemedicine domain is unclear, (3) comprehensive program budgeting has not occurred, and (4) partnerships with the private sector have not been fully explored. Further, DOD's telemedicine activities may be indicative of other federal agencies' telemedicine efforts.

Organizational Responsibilities Are Still Evolving

Many different DOD organizations generate telemedicine projects, including the ones shown earlier in table 3.1. The problems of organizational responsibilities are exacerbated by the large number of organizations involved in telemedicine activities.

In September 1994, the Assistant Secretary of Defense for Health Affairs designated the Army Surgeon General as the DOD Executive Agent for telemedicine and established the "DOD Telemedicine Testbed Project" to explore and develop new clinical approaches for using telemedicine. The Commander of the Army's Medical Research and Materiel Command was designated as the testbed's Chief Operating Officer, and the Command's Medical Advanced Technology Management Office (MATMO) was designated the principal manager and administrator for the testbed. However, the responsibilities for the Executive Agent, Chief Operating Officer, and MATMO were never approved in a charter.

Air Force, Navy, and other agency officials told us that an office similar to MATMO is needed to bring focus and coordination to telemedicine within

DOD. They also said that MATMO has been too focused on mainly supporting Army deployable telemedicine projects and excluding the other services' needs. It was difficult for us to distinguish between what MATMO initiates for the DOD-wide testbed and what it is pursuing for the Army. Most of MATMO's accomplishments are associated with the Medical Diagnostic Imaging Support system, which the Medical Research and Materiel Command was involved with before the Army became the DOD Executive Agent for telemedicine.³

Further, many service officials we met with, except from specific Army programs, were either not familiar with MATMO or were not getting guidance from them. For example, the Air Force program manager responsible for initiating a program in TRICARE Region 6, which Health Affairs expects to be a model for other TRICARE regions, had not received any assistance from MATMO in designing the program. The official told us that he relied on officials from the Medical College of Georgia for assistance. In addition, Navy telemedicine program officials at Camp Lejeune, North Carolina, were familiar with MATMO but relied on East Carolina University for advice. Further, this official stated that a group of TRICARE regions were attempting to develop their own coordinating mechanism on the Internet.

Other layers of oversight have evolved without clear responsibilities, with the Army fulfilling many key positions. Executive oversight of the testbed was vested in a Board of Directors, chaired by the Assistant Secretary of Defense for Health Affairs. Board members include the Director, Defense Research and Engineering; the Assistant Secretary of Defense for Command, Control, Communications, and Intelligence; the Joint Staff Director for Logistics; the three Surgeons General; and the Director of DARPA. At one point the Army Surgeon General served as both the Executive Secretary of the Board and as the Chief Executive Officer of the testbed. With the retirement of the former Army Surgeon General, the Navy Surgeon General became the Chief Executive Officer. However, the Chief Executive Officer's responsibilities have not been defined.

In addition, the Army Medical Department and MATMO had been responsible for overseeing evaluations of telemedicine projects, such as those being demonstrated in Bosnia. Army officials informed us that this

³The Medical Diagnostic Imaging Support is a filmless radiology system that has been operational at Madigan Army Medical Center at Fort Lewis, Washington—its first test site—since 1992. The system is also in operation at Walter Reed Army Medical Center, Washington, D.C.; Wright-Patterson Medical Center, Dayton, Ohio; Brooke Army Medical Center, San Antonio, Texas; and Tripler Regional Medical Center, Honolulu, Hawaii.

responsibility was being transferred to another service; as a result, the future of some of the Army's and MATMO's efforts was undecided. Other officials told us that the change was being made to prevent any conflict of interest on the Army's part, since the Bosnia telemedicine deployment is primarily an Army effort.

In August 1996, Health Affairs officials told us that its Information Management Proponent Committee would soon be responsible for providing oversight of telemedicine initiatives, including those under MATMO's purview. However, officials could not provide additional insight at that time regarding the concept of this structure.

In addition, another organizational change is underway that will impact on telemedicine, including DOD's research and development initiatives. In June 1996, the Deputy Secretary of Defense directed the Army to take the lead in establishing an Armed Forces Medical Research and Development Agency. The future impact of this new agency on the organizations responsible for telemedicine functions and funding is unknown.

Telemedicine Domain Is Unclear

A 1995 DOD Inspector General report suggested that DOD needed to define telemedicine more clearly.⁴ Without a consistent definition to describe telemedicine initiatives, responsible officials from the various DOD organizations participating in telemedicine efforts do not know precisely what their programs encompass. Although defense officials generally agree that telemedicine involves the use of communications technology to deliver health care, they have not agreed on the types of initiatives to include within the scope of telemedicine oversight. For example, some Army and DARPA officials consider patient identifiers that allow the electronic storage of medical information on a card or dog tag-like device to be the first element in an integrated telemedicine system, but the Navy does not view these devices in the same manner.

Air Force officials initially classified one of their projects as telemedicine but later said that the project fell outside of its definition of telemedicine. The project, called Provider Workstation, is intended to provide medical personnel with the capability to access medical records on a personal desktop computer no matter where the patient or the relevant information is located. Air Force officials now identify this project as one of its many medical management information systems. However, a 1996 DOD Inspector

⁴Telemedicine Demonstrations and Projects Directory, Department of Defense, December 1995.

General report noted that Provider Workstation was a successful DOD telemedicine project.⁵

Although MATMO tried to identify the full scope of telemedicine projects that might fall within its oversight function, our analysis revealed that its inventory (1) did not include the services' actual telemedicine efforts and DARPA-initiated projects and (2) contained inaccurate information. During the course of our review, MATMO and Health Affairs provided us information on six different inventories that included anywhere from 22 to 94 projects. In addition, a Health Affairs official told us that Health Affairs did not directly fund any telemedicine projects, but several telemedicine project managers informed us that they received funding from Health Affairs.

Program Budgeting Has Not Occurred

DOD has not developed a comprehensive telemedicine budget or program objective memorandum. In a 1994 memorandum to the Army Chief of Staff, the Director for Program Analysis and Evaluation noted that the concept of telemedicine needed to be defined by the Office of the Army Surgeon General to compete for funding during the budget process. Funding for telemedicine has been derived from other programs or congressionally directed.

Some service officials are especially concerned about budgeting for MATMO projects because MATMO managed about \$47 million during fiscal years 1995 and 1996 in telemedicine initiatives that were funded by Health Affairs or reprogrammed through the Medical Research and Materiel Command. Service officials have pointed out that MATMO does not have an approved funding line and therefore can operate outside the normal DOD development and acquisition process. As a result, none of MATMO's telemedicine projects are subject to milestone decisions, cost-benefit analyses, or life-cycle management decisions, which are all required in the acquisition process. MATMO officials believe that their approach is necessary at this time because technology is changing at such a fast pace that the normal acquisition cycle would prevent DOD from capitalizing on the newest telemedicine technology.

Partnerships With the Private Sector Have Not Been Fully Explored

Other than the telemedicine initiatives led by DARPA, few partnerships between the private sector and DOD are planned. The Medical Research and Materiel Command attempted to promote a collaborative working

⁵Evaluation Of Areas Of Consideration For A Department Of Defense Clinical Telemedicine Needs Assessment, Department of Defense, February 1996.

relationship between the Army and the private sector. The Command was planning to develop state-of-the-art telemedicine technologies—called the U.S. Army Federated Laboratory Concept—that are focused on combat casualty care. In May 1995, the Command issued a broad agency announcement. Interested parties were required to form consortiums involving health service providers, industry, and academia. Two parties whose proposals had not been accepted stated that DOD needed a more defined plan to which the private sector could respond. However, funding for the laboratory concept had not been programmed and was therefore subject to the availability of reprogrammed funding.

Although the Navy is seeking to form partnerships with academia, industry, and other government agencies, East Carolina University School of Medicine and Pitt Memorial Hospital, instead of Portsmouth Naval Medical Center, took the initiative to integrate the Camp Lejeune Naval Hospital in a telemedicine network. The TRICARE region that encompasses Camp Lejeune does not have a telemedicine strategy that identifies goals for pursuing such partnerships.

Also, according to Army Medical Department officials, the Army's Great Plains Health Service Support Area, responsible for managing medical care at Army facilities in 14 states and Panama City, has attempted to establish cost-sharing agreements with Texas Tech and a VA clinic in the area, but these attempts have been unsuccessful because of the lack of clear goals and objectives.

Private Sector Telemedicine Strategies Are Evolving

Given the wide range of private sector players in the implementation of telemedicine, it is understandable that no single private sector strategy exists to advance this emerging technology. For example, manufacturers develop new products, utility companies build the telecommunications infrastructure, professional organizations develop health care standards, health providers deliver medical care, and special interest groups promote the use of new technologies. Each of these groups has its own interests and strategies for advancing telemedicine.

Nonetheless, the private sector is an important player in furthering the development and application of telemedicine technologies. Two private sector health care providers—the Mayo Clinic and Allina Health Systems—and a major telecommunications company—American Telephone and Telegraph (AT&T)—illustrate the critical role played by the

private sector in advancing telemedicine and developing strategies for greater usage of this emerging technology.

Mayo Clinic

Telemedicine at the Mayo Clinic evolved to facilitate integration of group practices at three separate locations—Jacksonville, Florida; Scottsdale, Arizona; and Rochester, Minnesota. In 1986, the Mayo Foundation installed a satellite-based video system that enabled physicians, researchers, educators, and administrators to communicate with each other. When the Jacksonville and Scottsdale facilities were not fully staffed, they used specialists from Rochester via telemedicine for four or five consultations per week. However, with the addition of specialists at the Jacksonville and Scottsdale locations, the telemedicine system was increasingly used for education, research, and administrative purposes. According to Mayo, in 1995, its telemedicine system was used for over 700 telemedicine consultations in echocardiology between Rochester and the other two sites.

Mayo is also involved in a project supported by NASA and DARPA to explore the combination of satellite communication and terrestrial services in an economic telemedicine model. To conduct the project successfully, Mayo has assembled a consortium of leaders in the industry (Hewlett-Packard, General Electric Medical Systems, Sprint, U.S. West, Martin Marietta, Healthcom, and Good Samaritan Hospital in Arizona), along with Mayo Foundation entities. The results from this project will help determine a strategic policy for telemedicine at the Mayo Clinic and provide knowledge about the use of asynchronous transfer mode technology for local area and wide area networks. Mayo officials told us that there has to be a need for which telemedicine is a solution—otherwise telemedicine applications will not be financially viable. These officials believed that managed care organizations may ultimately drive the development of telemedicine.

Allina Health Systems

A representative from Allina Health Systems, a managed care organization and insurer from Minneapolis, Minnesota, stated that the market will determine the pace and extent to which it expands its telemedicine services. Along with an alliance of eight rural hospitals, Allina has operated since 1995 a telemedicine network that links hospital emergency rooms. Allina believes that emergency medicine in rural areas is the best application of telemedicine currently available for its operation. As of October 1996, Allina's telemedicine network had been used for about 130

medical consultations and about 450 emergency service consultations. Allina's network is a single-state system, which eliminates concerns about licensure requirements that plague many telemedicine efforts. The use of Allina's telemedicine network in urban areas is quite different than its use in rural areas. For example, in urban areas there is more extensive use of the system for administrative and educational purposes and virtually no use for consultative purposes.

Allina recognizes the need for better cost-benefit data to justify major investments in telemedicine and prove that the applications are worthy. Toward this goal, the company plans to improve the development of project evaluations and its marketing strategy.

Allina must decide in the near future whether to view its telemedicine initiative as a service and thus a cost of business or as a separate business entity or profit center. One of the complicating issues is that so many variables in measuring costs are difficult to separate (i.e., normal operating costs versus special costs associated specifically with telemedicine).

AT&T

AT&T's strategy for telemedicine development involves developing services for telecommunication applications, transactions, and networking and providing telecommunications and some training for computer-based medical systems. These efforts have accelerated since the creation of the National Information Infrastructure. AT&T's involvement in telemedicine efforts is largely due to the company's perception, which was confirmed by clients, of a need for reliable and secure communication lines for health care.

AT&T is making a substantial investment—both financially and from a personnel resource perspective—in telemedicine development. For example, an official told us that by December 1996 AT&T expected to assign about 100 staff members to servicing or managing one agency's telemedicine system.

Even though it has contracts with federal agencies and is assisting many private sector groups, AT&T plans to seek FDA review of its products and services. AT&T said that many products involving telemedicine are possible but that customers may not be willing to pay for them. As a result, manufacturers must make certain that there is a market for the products being developed.

Agency Comments and Our Evaluation

HHS commented that our report should acknowledge the role that the High Performance Computing and Communications Program has played in the coordination of federal telemedicine research and development activities. During our review, we collected data from the National Library of Medicine on funding from this program specifically for telemedicine initiatives. However, agency officials did not highlight to us the role that this program plays in coordination of telemedicine activities across the federal government or with JWGT. We believe that the program is one of several federal initiatives supporting telemedicine initiatives. However, we did not evaluate the program, since it was beyond the scope of our review.

Telemedicine Benefits Are Promising but Largely Unquantified

Telemedicine offers numerous benefits for the military, other federal and state government organizations, the private sector, and individual patients because it eliminates distance as a factor in treating patients. Such benefits include access to care where it is not otherwise available; improved quality of care; and, in many instances, reduced costs. However, costs could increase due to investments in infrastructure and increased utilization of health care services. No comprehensive studies have been completed to prove that telemedicine delivers cost-effective, quality care. Early efforts included few consultations and only provided anecdotal, or retrospective, observations about the benefits. Several federal agencies and the private sector are beginning to implement some comprehensive studies, but results from most of these studies will not be known for several years.

Telemedicine Provides Benefits to Various Groups

By eliminating distance as a factor in treating patients, telemedicine benefits health care providers and patients, no matter whether the setting is a military site, rural hospital, or correctional facility. Without telemedicine, persons who need specialized care could be left untreated; improperly treated; or, if time and circumstances permitted, transferred to another facility for the care.

Telemedicine provides benefits to the various groups by allowing access to care where it is not otherwise available and improving the quality of care delivered. In addition, telemedicine may, in many instances, reduce health care delivery costs.

Telemedicine Allows More Access to Health Care

For the medic on the battlefield, telemedicine provides immediate access to a clinician with greater skills so that they can work together to save a soldier's life. DOD believes telemedicine could reduce the mortality and morbidity rates on the battlefield by as much as 30 to 50 percent. Quality trauma care depends on the timely, efficient, and accurate flow of information at each step of the crisis management process. Telemedicine can provide the vehicle for this flow of information, which includes patient information, treatment records, and medical knowledge.

Telemedicine could provide a "bridge" for the 100,000 to 150,000 personnel deployed on military ships around the world who have limited access to medical diagnostic and consultant services. For example, during a 6-month Western Pacific deployment in 1995, sailors aboard the aircraft carrier U.S.S. Abraham Lincoln had access to enhanced specialist medical care

from the Naval Medical Center in San Diego, California, 6,000 miles away. That access proved critical for one sailor who injured his hand on a gun mount. The injured sailor was transferred from another ship to the Abraham Lincoln with the gun mount part still implanted in his hand. X-rays and video of his injury were transmitted to San Diego where a specialist consulted with the ship's surgeon to treat the injury. The sailor returned to light duty on his ship 3 days later. Another case involved a sailor aboard the U.S.S. Enterprise who sustained a neck injury on the flight deck. Immediate telemedicine consultation was able to rule out a cervical fracture.

For peacetime military health care, telemedicine allows remote military treatment facilities to link up with DOD medical clinics to obtain specialized health care. Similarly, telemedicine allows rural communities to communicate with larger medical facilities to obtain specialized care. For example, a physician in remote Montana can send a trauma victim's x-rays to a large hospital in Seattle, where a radiologist can confirm that the patient has a broken vertebra and needs to be evacuated immediately.

The states and private sector can also benefit from improved access to health care. For example, an emergency medical technician on an ambulance call or at a disaster site can use telemedicine to provide immediate access to an emergency room physician who has greater knowledge and can provide guidance to the technician to perform skilled procedures to save an individual's life or limbs. Improved access to health care is especially important to patients in remote areas. For example, the University of Washington's telemedicine network serves four communities in remote locations in the states of Washington, Alaska, Montana, and Idaho. Each site is located in an area with rugged terrain and extreme cold weather, which can make travel extremely dangerous or impossible.

In addition, the Georgia Statewide Academic and Medical System is dispersed among 60 health care facilities to ensure that all state residents have immediate access to quality health care. Many of the state's large, poor rural populations may lack adequate access to health care without traveling long distances. Of the state's 159 counties, 9 have no physician, 85 have no pediatrician, and 140 have no child psychiatrist.

Finally, telemedicine may allow physicians to provide medical care to patients in their homes. For example, VA's Eastern and Western Cardiac Pacemaker Surveillance Centers routinely use standard telephone lines to monitor the electrocardiograms of pacemaker patients from their homes.

A 1996 VA testimony indicated that the surveillance centers save time and effort, provide pacemaker expertise to remote and underserved areas, and decrease the need for pacemaker clinic appointments. In addition, pacemaker monitoring improves health care quality and is convenient for veterans, since they can be monitored 24 hours a day from any place that has a telephone. VA estimates it has made over 386,000 "house calls" from 1982 to 1996, or about 2,300 a month, using this system.

In another effort, the Army's Center for Total Access at Eisenhower Army Medical Center joined the Medical College of Georgia, the Georgia Institute of Technology, and a local cable company to develop a telemedicine home health care network, known as Electronic Housecall. This program, which became operational in February 1996, links a nursing home and the homes of 25 chronically ill patients with their health care providers. Through daily monitoring, the health care practitioners should be able to detect early changes in the patients' condition. If practitioners find changes, they can prescribe a different treatment or request that patients come in and see their physician. By detecting problems earlier, hospital stays may be avoided or reduced. Each patient selected for this project was chronically ill and averaged six or more hospitalizations per year at an average cost per hospital stay of about \$25,000.

Telemedicine Can Improve Health Care Quality

Telemedicine gives health care providers a chance to enhance their skills and expand their professional knowledge by linking providers with experts. In remote locations, health care is provided by general practitioners. When the practitioner believes a patient needs specialized care, the practitioner frequently has to refer the patient to a specialist in a different location and may not be present in the consultation between the patient and the specialist. With telemedicine, the general practitioner is present during the consultation and can learn from the specialist. Telemedicine advocates expect that such experiences will increase a practitioner's medical knowledge, which in the future may help the practitioner to diagnose and treat illnesses earlier or determine that the patient needs to see a specialist right away.

Enhanced knowledge would have been helpful to general practitioners and medics during the Vietnam War. According to an Army dermatologist, if telemedicine had been used during the war, the number of hospitalizations, evacuations, and days lost due to skin diseases could have been reduced by about one-third. Skin disease was the primary reason for outpatient visits to Army medical facilities during the war.

Between 1968 and 1969, skin diseases accounted for 47 percent of total days lost for the U.S. 9th Infantry Division. According to the dermatologist, if the general practitioners and the medics at the forward facilities had been able to consult with skin specialists via telemedicine, they would have learned to recognize and treat skin diseases earlier.

Telemedicine also has the ability to deliver continuing medical education to deployed medical units and remote health care practitioners so that they have the opportunity to enhance their professional knowledge without having to travel. For example, medical units in Bosnia received weekly continuing education classes via telemedicine from a DOD medical center in the United States. Two of the classes covered acute care of burn victims. One week after the classes, two soldiers in Bosnia were severely burned in an explosion. The medical unit used what it had learned in the classes to stabilize and treat the soldiers until they could be transferred to a facility with more skilled care. According to medical unit personnel, without the classes the soldiers would not have received the same quality of care at the site.

The Medical College of Georgia offers one continuing professional education credit for the referring health care practitioner participating in telemedicine consultations. The University of Washington's School of Medicine is the only medical school directly serving the states of Washington, Alaska, Montana, Idaho, and Wyoming. The medical school operates a medical education program via a telecommunications network to affiliate teaching facilities in these states. In California, a health maintenance organization provides continuing medical education over its telecommunications networks. One of the organization's programs delivers monthly lunch-hour medical education classes that reach about 1,000 of its 3,500 physicians.

Many Examples Identify Cost Savings

An Arthur D. Little Foundation study published in 1992 on the U.S. health care crisis said that just the video conferencing component of telemedicine used for remote medical consultations and professional training could reduce health care costs annually by over \$200 million. For example, video consultations can shorten diagnostic time, reduce treatment time, and decrease hospital stays. Telemedicine can also reduce evacuation or travel costs incurred when patients and specialists have to travel for consultations.

Several service officials believe that telemedicine's biggest cost benefit to DOD will be its application to the reengineering of health care delivery during peacetime. In fiscal year 1997, MHSS' budget is over \$15 billion and includes 115 hospitals and 471 medical and dental clinics operating worldwide.

In a case involving 12 patients over a 4-month trial period, Eisenhower Army Medical Center's critical care telemedicine project with Fort Stewart's hospital saved DOD at least \$54,000 in transportation costs and expenses associated with the Civilian Health and Medical Program of the Uniformed Services. Two patients did not need to be transferred to Eisenhower or the local hospital, and one patient's stay at a non-DOD hospital was shortened. Teleradiology used on a 4-month deployment of the U.S.S. George Washington in the Mediterranean Sea and Indian Ocean eliminated the need for 30 evacuations and saved about \$100,000. Telemedicine also saved DOD \$63,000 in evacuation costs during its deployment to Somalia.

Telemedicine can provide cost savings to states in prison health care transportation costs. For example, since Georgia began using telemedicine in its prisons in 1993, only about 25 percent of the prisoners seen via telemedicine had to be transferred to another facility for further treatment. In the first 10 months of 1995, 218 consultations were done, saving between \$82,000 and \$246,000 in transportation costs for those consultations that did not result in a transfer to another facility. In Texas, the Department of Criminal Justice contracts with the University of Texas Medical Branch at Galveston and Texas Tech Health Sciences Center to provide health care to its inmates in correctional facilities. In the first 20 months of operation, 2,607 telemedicine consultations were conducted with high patient satisfaction. An evaluation showed that about 96 percent of the consultations saved at least one trip to the Galveston Medical Center at an estimated cost of about \$190 per trip, or about \$495,000.

Telemedicine can also provide savings in hospital costs. Initial data from the Medical College of Georgia showed that over 80 percent of patients seen via telemedicine did not need to be transferred from their primary medical facility to a specialized care facility. Given the cost difference of between \$500 and \$740 per day per bed between rural hospitals and the Medical College of Georgia, cost savings resulting from telemedicine may be significant. In Minnesota, a managed health care company and a rural health care company formed a partnership to develop a rural telemedicine network. As part of this network, eight rural hospitals were connected to a

larger community hospital for emergency room consultations. Early indications have pointed to overall cost savings for the participating facilities. For example, one referring rural hospital was able to decrease its emergency room operating costs by \$47,500 a year, even after paying an additional \$50,000 fee to the community hospital for consultations. Due to the increased referrals from the eight rural hospitals and the yearly fees, the community hospital was able to eliminate its yearly \$300,000 emergency room operating deficit.

In addition, because telemedicine brings specialized health care to the patient, the patient does not need to take as much time away from work or duty to receive care. This results in increased productivity for the worker and the employer and fewer lost wages. In DOD's case, reducing the time away from work results in increased readiness of its military forces. For example, Tingay Dental Clinic at Fort Gordon, Georgia, used telemedicine to provide specialized dental consultations to active duty personnel at Forts McPherson and Benning, Georgia; Fort McClellan, Alabama; Soto Cano Air Force Base, Honduras; Gorgas Army Hospital, Panama; and the Naval Dental Detachment, Key West, Florida. Without these consultations, the soldiers would have to take time away from duty and travel for specialized dental care. A study done by the clinic showed that soldiers at Fort McPherson saved at least one-half day away from duty for each consultation.

A telemedicine project at Fort Jackson, South Carolina, decreased the amount of time a soldier missed basic training. Typically, a soldier on sick call would lose a whole day of training because of the time to drive to the clinic, wait to see the physician, get a prescription filled, and return to the field. Of 101 soldiers seen via telemedicine, about 20 percent returned to training without going to the clinic. DOD officials believe that as the practitioners get more familiar with the equipment and the medical procedures are streamlined, more than 50 percent of the soldiers will be able to return to training without going to the clinic.

Potential Savings May Be Offset by Infrastructure Costs and Increased Use

Although some data show that telemedicine can save costs, other data indicate that there is a high cost for using telemedicine both in total dollars and per consultation. Main factors include infrastructure start-up costs and operational costs of the systems and equipment. For example, the infrastructure start-up, equipment, and operational costs for DOD's telemedicine deployment to Bosnia are estimated to total about \$30 million, and only about 60 consultations, excluding teleradiology

cases, have been performed to date. Also, recurring basic telemedicine line charges in rural communities can run about \$1,500 a month. Various officials expressed concern whether the volume of rural telemedicine consultations can ever be high enough to pay the recurring line charges as well as initial equipment expenditures.

Another factor that will affect the cost of telemedicine is increased utilization by persons who previously did not have access to such care. According to the Institute of Medicine's report on telemedicine, home monitoring via telemedicine may result in earlier identification and treatment of problems that would be more costly to treat if not caught early, but it may also identify more borderline problems that would generate more home or office visits.¹

The potential cost impact of inappropriate utilization of health services via telemedicine is a concern for many third-party payers, such as Medicare. These concerns are not as apparent in managed health care settings, including DOD and VA, where many costs are fixed, including physician salaries. On the other hand, fee-for-service providers receive their income from the volume and type of services provided. In such settings, some providers may use complex and costly medical technologies when less costly techniques may suffice.

Without a payment support mechanism, infrastructure or health care providers may not consider telemedicine alone to be capable of delivering a sufficient return to justify their investment. However, if multiple applications are available to use the infrastructure, such as those related to business, education, or entertainment, the infrastructure cost can be shared among the various users.

Officials at the Health Care Financing Administration (HCFA) are also concerned that Medicare expenditures could significantly increase if Medicare were to begin reimbursing for telemedicine consultations. Various reports have cited an estimate that telemedicine consultations could increase the total Medicare budget by \$30 billion to \$40 billion annually by the year 2000. Our review found no evidence to support this increase. HCFA officials indicated that the agency could not estimate what the impact would be to the Medicare budget if the federal government began reimbursing for telemedicine consultations, but the amount should be much less than the \$30 billion to \$40 billion increase cited by various reports.

¹Telemedicine: A Guide to Assessing Telecommunications in Health Care, Institute of Medicine, 1996.

Cost-Effectiveness of Telemedicine Has Not Been Analyzed

Although many individuals strongly believe that telemedicine is a good value, no one has quantified the benefits through a comprehensive cost-benefit analysis. Evidence supporting these beliefs is mainly based on anecdotal examples, small retrospective reviews, or personal opinions. In fact, the lack of comprehensive evaluations was a major theme throughout the 1996 American Telemedicine Association Conference. In the past, such studies have not been done because adequate sample sizes were not available or the financial resources for conducting the evaluations were lacking. However, several agencies are now funding or conducting comprehensive studies.

Early Studies Focused Primarily on Technical Feasibility

Early telemedicine programs concentrated on demonstrating that the technology would enable the health care practitioner to diagnose and treat patients at remote sites. The primary focus was on whether the technology worked, and cost-benefit analyses were not built into these early projects.

Despite 12 telemedicine deployments since 1993, DOD's only documented studies appear in three articles in professional journals. DOD has compiled some lessons learned from Army deployments, the Advanced Warfighter Experiments, and Joint Warfighter Interoperability Demonstrations. These studies, however, had a limited scope and raised additional questions.

A 1996 Army study on telemedicine deployments showed that telemedicine significantly changed the diagnosis in 30 percent of the cases seen and the treatment in 32 percent of the cases. However, the study noted that because of limitations, such as lack of follow-up and outcome data, response time, and user satisfaction, the data may provide limited results. Additionally, the exclusion of incomplete records may have also skewed the results. For example, the use of telemedicine may have precluded air evacuations, but there was little or no information on whether the patient had a worse outcome or needed evacuation after the consultation. Because of the lack of a central records system, it was impossible to follow individual cases to determine case outcomes.

This study also noted that the types of patients seen in operations other than war differ from those seen in active combat, suggesting that the results may not be indicative of the benefits of battlefield telemedicine. For example, combat support hospitals are staffed to treat previously healthy young soldiers suffering from trauma and are not configured for pediatric patients and chronic infectious disease cases. The study concluded that further analysis may help determine if a combat support

hospital in an operation other than war needs modification. It also suggested that the large number of dermatology consultations may indicate that dermatologists should routinely deploy with combat support hospitals.

During its Advanced Warfighter Experiments in 1994 and 1996, the Army Medical Department demonstrated that medics using lightweight, hands-free, two-way radios were able to communicate with medical officers at battalion aid stations to provide lifesaving medical treatment. This communication impacted the number of soldiers who may have never been evacuated off the battlefield. However, few trends become apparent from analyzing the data from the different experiments. Some data showed that medics utilized the consultations more if the number of casualties was small. As the number of casualties increased, consultations went down. Because the time required to treat each casualty increased, other wounded could die while the medic was in a consultation. The Joint Warfighter Interoperability Demonstrations showed that the different services' medical communication systems were incompatible with each other and the warfighter.

Early rural health demonstrations have also provided some lessons learned about network structure, personnel, funding, and equipment considerations when establishing telemedicine networks. For example, HHS' Office of Rural Health Policy (ORHP) compiled results and preliminary lessons learned from 1995—the first year of experience of 11 of its 25 telemedicine grantees—but it is too early to know whether these projects will be successful in improving access to care for rural residents. It is also unclear how the projects will affect the multispecialty hospitals, rural hospitals, and clinics that are part of these networks. Further, an ORHP internal study reported that developing a telemedicine network is complex, requiring coordination and cooperation from multiple players both within and outside the health care arena.

DOD Telemedicine Evaluations Are Not Coordinated Among Services or Facilities

A number of DOD organizations are planning and implementing telemedicine evaluations. However, there is little coordination among the sites in developing these evaluations. In addition, the evaluations may not be used outside each organization to develop a DOD-wide database or collective evaluation to provide DOD policymakers with data they can use to establish a DOD strategic plan or prioritize funding.

Some TRICARE regions are planning to evaluate telemedicine costs and benefits. Tripler Regional Medical Center in Hawaii allocated \$700,000 to fund an evaluation of its telemedicine initiatives. The evaluation will address (1) clinical outcomes, (2) patient and provider satisfaction, (3) costs and benefits, (4) human behavior factors such as personnel and training, and (5) organizational impact. According to officials, the telemedicine protocols and evaluation tool were developed without coordination with other TRICARE regions, although they were shared among DOD agencies during an August 1995 workshop in Hawaii on telemedicine evaluation methodologies.

Two separate evaluations are planned for Madigan Army Medical Center's teleradiology and telemedicine systems. The teleradiology evaluation, being developed and conducted by a Department of Energy contractor, will address the impact of the Medical Diagnostic Imaging Support/teleradiology on radiology operations, procedures, costs, and patient satisfaction.

The evaluation of other telemedicine systems will identify (1) the impact of telemedicine procedures on the costs of collecting clinical information for consultations conducted at the military treatment facilities and VA's Puget Sound Healthcare System and (2) the correlations of user and service characteristics to clinical information acquisition costs of telemedicine procedures. The study will result in lessons learned and a proposed methodology for future projects. VA's medical center in Seattle is developing the study, which will be tested at all DOD and VA facilities in the Puget Sound area. The VA official responsible for developing the evaluation said that she has not received any input or assistance from DOD personnel, except for Madigan Army Medical officials.

The Center for Total Access plans to evaluate its telecardiology program once it is operational. Center personnel are working with a MATMO contractor that is developing software, including cardiac protocols or standardized procedures. The Center's director was unaware that a project at Tripler Regional Medical Center had already developed cardiac protocols.

Wilford Hall Air Force Medical Center in San Antonio is planning to conduct a cost-benefit analysis of some of its telemedicine efforts. A goal of the analysis is to compare average costs per consultation for certain specialties with and without telemedicine. The project will gather information on referral patterns to the specialties and sites. This

information will then be used to calculate an average cost to the government per consultation by site and specialty. The study will examine both active and non-active duty patients. Officials have not developed an approach to coordinate the evaluation with other TRICARE regions.

Civilian Agencies Are Conducting Wide-Reaching Evaluations

Other federal agencies that are now funding or conducting large-scale, comprehensive evaluations of telemedicine include VA, the National Library of Medicine, HCFA, ORHP, and the Agency for Health Care Policy and Research. However, these evaluations are in the early stages and frequently have not been coordinated among or within agencies.

Several civilian agencies have recently required their grantees and contractors to perform evaluations as part of their projects. Because most of these projects have not reached completion, evaluation results have not been reported. Some of these evaluations examine broad issues, and some will have a limited focus. For example, each HCFA telemedicine payment demonstration grantee in Iowa, Georgia, North Carolina, and West Virginia is evaluating the costs and benefits of reimbursing specialists for providing medical services via telemedicine to Medicare patients.

Eleven of ORHP's 25 telemedicine grantees will evaluate the relative effectiveness of their telemedicine project in a rural environment and identify barriers to effective implementation. Similarly, one project involving six rural Texas communities, funded by the Agency for Health Care Policy and Research, includes an analysis of the factors that facilitate or hinder the long-range commitment to telemedicine use for interactive video and continuing education.

Each of the 22 contractors involved in the National Library of Medicine's High Performance Computing and Communications Program will evaluate the impact telemedicine can have on health care access, quality, and cost. For example, a hospital in Boston will use telemedicine to provide educational and emotional support to families of high-risk newborns both during their hospitalization and following discharge. The program will examine the potential of telemedicine to decrease the cost of care for infants with very low birth weights by increasing the efficiency of care.

A number of federal civilian agencies are working with the private sector to conduct comprehensive evaluations of telemedicine. For example, in fiscal year 1996, ORHP awarded \$200,000 for the Telemedicine Research Center of Portland, Oregon, to develop a standard data set for

telemedicine evaluation and conduct an objective and scientific evaluation of telemedicine programs. The project will last 2 years and cost \$330,000. The purpose of the project is to collect basic information about the operations, utilization, costs, benefits, and sustainability of the rural telemedicine projects that ORHP funds. This report is expected to be issued in 1998.

The evaluations will also develop an evaluation methodology rather than assess the success of a specific telemedicine project. For example, an Institute of Medicine study, titled "A Guide to Assessing Telecommunications in Health Care," develops a framework for evaluating telemedicine's effects on the quality, accessibility, costs, and acceptability of health care compared with alternative health services. The framework includes strategies or questions that could be used by anyone planning to perform an evaluation. One question is whether a teledermatology consultation provides the same quality of patient care and therefore the same outcome as a face-to-face consultation. Another question is whether the teleconsultation result provides more timely access to the dermatologist than a scheduled face-to-face consultation. Officials hope that this framework will standardize evaluations enough to promote comparability so that the results from individual studies can be combined to provide the evidence needed to quantify the benefits of telemedicine.

JWGT also developed a discussion paper outlining a broad evaluation framework for telemedicine. The goal of this paper was to provide a document for an entity to design its own evaluation to meet its needs but at the same time be comparable to other studies. The Puget Sound VA evaluation will closely follow JWGT's evaluation framework paper.

Other evaluations will be follow-up or more comprehensive views of specific grants that had required their own evaluations. For example, ORHP sponsored a study by Abt Associates to estimate the use of telemedicine in rural hospitals and identify and describe those rural hospitals that are actively involved in telemedicine. The initial screening survey generated valuable information about the extent of telemedicine use in rural communities, but it also raised many new questions that must be addressed through a detailed follow-up survey. The final report, which included an in-depth follow-up survey, was issued in December 1996. Among other issues, the report addressed utilization, technologies employed, infrastructure costs, and accessibility.

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In another case, HCFA has signed a cooperative agreement with the Center for Health Policy Research at the University of Colorado to evaluate the effects of teleconsultation payments on access to services and quality of care for the five telemedicine projects HCFA supports. Under these projects HCFA will experiment with alternate payment schemes, including separate payments to providers at each end of the network as well as a single "bundled" payment to cover both providers. The center will collect information about diagnoses, health service utilization, patient and provider satisfaction, quality of care, and patient outcomes. This report is expected to be issued in early 2000.

Several Barriers Limit Telemedicine Activities

Several barriers, in addition to the lack of project evaluation, prevent patients and providers from realizing widespread benefits of telemedicine. Experts in telemedicine generally agree that these barriers can be primarily categorized as legal and regulatory, financial, technical, and cultural.¹ Legal and regulatory barriers involve such issues as interstate licensing, malpractice liability, privacy and security, and regulation of medical devices. Financial barriers relate to reimbursement of providers and high infrastructure costs. Technical barriers are created by lack of standards and equipment incompatibility. Cultural barriers involve physician and patient acceptance. Most U.S. telemedicine networks that are not limited to teleradiology enjoy some financial support from federal grants and contracts for limited periods. Unless these networks can overcome telemedicine barriers, their sustainability is jeopardized once federal support lapses.

Barriers Hamper the Private Sector More Than the Federal Sector

The private sector, particularly fee-for-service providers, is generally affected by all barriers—legal and regulatory, financial, technical, and cultural. Federal sector agencies that directly deliver health care services, such as VA and DOD, are less affected than the private sector by legal and regulatory barriers, but cultural (particularly physician acceptance) and technical barriers hinder both sectors' development of telemedicine. However, VA has an extensive telecommunications system that is available for health care applications. As a result, DOD, the Indian Health Service (IHS), BOP, and VA may be better positioned to advance the development of telemedicine. Figure 5.1 shows the segments that are affected by each of the barriers we have identified. Many groups and organizations in the public and private sectors are working individually and as partners to develop strategies and options for overcoming barriers to telemedicine.

¹Telemedicine literature, reports, interviews with selected federal agencies, national medical specialty groups, and other organizations provided an in-depth review of the key barriers and validated their impact on the implementation of telemedicine.

Table 5.1: Specific Telemedicine Barriers Impacting Government and Private Sector Entities

| Barrier | Government | | | | Private sector | |
|--|------------|----|-----|-----|----------------|-----------------|
| | DOD | VA | IHS | BOP | Managed care | Fee for service |
| Legal and regulatory | | | | | | |
| Licensure | | | | | X | X |
| Malpractice liability | | | | | X ^a | X |
| Privacy and security | X | X | X | X | X | X |
| Regulation of medical devices | X | X | X | X | X | X |
| Financial | | | | | | |
| Lack of reimbursement | | | | | | X |
| High infrastructure costs | X | | X | X | X | X |
| Technical | | | | | | |
| Lack of standards | X | X | X | X | X | X |
| Technology performance and equipment compatibility | X | X | X | X | X | X |
| Cultural | | | | | | |
| Physician acceptance | X | X | X | X | X | X |
| Patient acceptance | b | b | b | b | b | b |

^aA managed care organization may be exposed to additional malpractice liability suits when its patients or health care providers consult via telemedicine with physicians outside the organization.

^bThe extent of the problems presented by this barrier is unknown.

Legal and Regulatory Barriers

Legal and regulatory barriers to implementing telemedicine activities are licensure issues, malpractice liability, privacy and security, and regulation of medical devices. These barriers will require federal, state, and private efforts to solve them. Federal and state health policymakers and working groups representing federal and private sector interests (including national organizations and companies) are working individually and collectively on approaches for overcoming these barriers. As a focal point, JWGT is conducting an in-depth review of legal and regulatory barriers, among others, to gain a clearer understanding of the impediments that hinder the advancement of telemedicine.

Requirements for Multiple Medical Licenses

According to individuals we contacted and literature we reviewed, one of the major legal barriers encompasses the licensure of health care professionals providing telemedicine services in multiple states. In the

United States, physicians must be licensed in each state in which they practice medicine to protect the health, safety, and welfare of the public. One issue facing many states is whether a physician who provides medical advice to someone in another state via telemedicine is in effect practicing medicine in the patient's state. Another issue is that obtaining and maintaining licenses in other states can be a time-consuming and expensive effort.

For physicians who regularly or frequently engage in the practice of medicine across state lines, the Federation of State Medical Boards of the United States, a private organization, developed a model act in April 1996 that would create a special license for physicians to practice telemedicine in a state where they are not currently licensed. If the model act is adopted by states, this special license could remove the need for physicians to obtain a full license in each state where they practice telemedicine. Physicians who merely consult with other physicians in certain states concerning medical diagnosis and treatment, however, are less likely to encounter licensing barriers than physicians having direct and frequent contact with patients in other states. In opposition to the model act, various national associations, such as the American Medical Association, recommended full and unrestricted licensure by individual states for physicians who wish to practice telemedicine across state lines. In contrast, the National State Board of Nursing has recommended one national license instead of numerous state special licenses.

Our review of literature and other reports revealed that some states are beginning to restrict medical practice through telemedicine. At least 12 states have taken specific action regarding licensure of out-of-state physicians. Of the 12 states, 10 require out-of-state physicians to be licensed in their states. In the 11th state, Florida, out-of-state physicians who conduct telemedicine services do not need a Florida license as long as the physician who ordered medical services is authorized to practice medicine in Florida. In the 12th state, California, the state's medical board is authorized to establish a registration program that would permit a practitioner located outside the state to practice in the state upon registration with the board.

Licensing is generally not a barrier for federal agencies. Federally employed physicians who treat patients in government facilities are required to be licensed in only one state, which does not have to be the one in which they are practicing. However, if a federal physician treats a patient not eligible for federal benefits, the physician is required to have a

license in the patient's state. Similarly, licensing would apply if, for example, a VA hospital joined a telemedicine network that included private hospitals and VA physicians were required to see private patients. This licensing requirement would generally apply to all federal physicians.

Malpractice Liability

Malpractice exposure is always present in a doctor-patient relationship. The risk of additional malpractice liability constitutes another barrier to the practice of telemedicine in the private sector, particularly in networks that cross state lines. There is uncertainty whether a physician who uses telemedicine to "see" a patient in another state will be subjected to the jurisdiction of the courts in the patient's state.

Fundamental issues regarding telemedicine encounters remain vague. In its March 1996 report, the Council on Competitiveness noted that the issue of malpractice is perhaps the greatest unknown barrier.² The Council believes that a key question is whether a distant physician who performs a telemedicine consultation will be held subject to the jurisdiction of the courts in the patient's judicial district. It is unclear under what circumstances a remote encounter via telemedicine could subject a practitioner to malpractice litigation in the remote state. For example, one report suggests that the risk of malpractice is heightened when the practitioner is in one location and the patient, in another location, is in the presence of only a nurse or physician's assistant. Even when physicians are at both ends of the telemedicine transmission, the specialist who guides or supervises the less skilled physician performing the procedure could be sued in a distant court for malpractice.

Given this uncertainty and the relatively little guidance that the small number of lawsuits throughout the country can offer, the malpractice insurance industry is still considering whether the expansion of telemedicine requires a change in coverage to specifically include telemedicine in rating bases. Thus, if an individual physician believed his or her malpractice coverage was not sufficiently comprehensive to include the many facets of telemedicine, that practitioner's willingness to engage in telemedicine could pose a barrier.

These concerns are also expressed by the American Medical Association, which believes that the law is currently unclear where liability falls when two or more practitioners cooperate on a medical problem using

²Highway to Health: Transforming U.S. Health Care in the Information Age, Council on Competitiveness, March 1996.

telemedicine. One representative of an association of physician-owned malpractice insurance companies told us that she was aware of only four malpractice suits concerning telemedicine (all of which were settled out of court), but she believed that others might reach the courts soon because of the length of time for a case to come to trial.

Medical malpractice issues in the federal sector differ from the private sector. In the federal sector, the controlling law is the Federal Tort Claims Act (FTCA),³ which for more than 40 years “has been the legal mechanism for compensating persons injured by negligent or wrongful acts of Federal employees committed within the scope of their employment.”⁴ FTCA provides that a suit against the United States for a wrongful act or omission by a federal employee or officer shall be the exclusive remedy permitted to a claimant and that no federal employee can be sued. Additionally, parallel provisions pertaining to VA, DOD, and HHS expressly state that malpractice and negligence suits against medical personnel of those agencies are barred and that the exclusive remedy is an action against the United States. Therefore, even though telemedicine is a potential cost to the government, the threat of malpractice suits against individual federal physicians is not a barrier.

The protections of FTCA generally extend only to federal employees and officers acting within the scope of their employment and authority. The protections generally do not apply to a contractor of the United States. To date, no suits have been filed against the federal government involving telemedicine. Such suits, which are decided according to the law of the jurisdiction where the act or omission occurred, may help determine the scope of liability of the federal government for the practice of medicine.

In the private sector, medical malpractice suits may be vulnerable to “venue shopping,” under which a patient can elect to bring suit against a practitioner in any state where that practitioner does business, regardless of where the act or omission occurred. A physician or institution that practices medicine in multiple states could be sued, therefore, in the state where jury awards are most favorable, even if the particular telemedicine consult being sued upon occurred elsewhere.

³28 U.S.C. Sections 2671 and 2679.

⁴28 U.S.C. Section 2671 note.

Privacy and Security of Medical Data

Another barrier to widespread deployment of telemedicine applications and computer-based patient record systems is the public's concern that the privacy and security of personally identifiable medical data will be jeopardized. One example that underscores concerns over the handling of medical records involved the leak of a confidential list of Pinellas County, Florida, residents with AIDS (Acquired Immune Deficiency Syndrome). The release of this list, which was on computer disc and had close to 4,000 names, revived concern about the proper handling of sensitive medical records.

Among many federal agencies, there is strong interest in the development and use of computer-based patient record systems and other transmission of medical data via telecommunications networks in support of patient care, clinical research, health services research, and public health. An integrated information system (1) allows medical providers to have access to a patient's medical record, even if the paper record is not available, and quickly assembles patient information from multiple sources (x-rays, pharmacy, and lab). Once this information is assembled, provider organizations, practitioners, payers, and the public sector would be able to move critical information among themselves. Such exchanges may enhance the ability of providers to render services across the continuum of care, reduce duplication, and improve the quality of care.

The benefits of an integrated information system come with risks. A 1995 report from the Physicians Payment Review Commission acknowledged that the benefits of data integration capabilities offered by telemedicine systems are accompanied by risks of violating a patient's right to privacy.⁵ The report stated that patients' data privacy rights should be protected by obtaining a patient's permission before participating in teleconsultations, including written agreement for recording of sessions and storage of tapes as part of medical records. Further, using data protection techniques during transmission could prevent disclosure. Even when patients are properly informed about the transmission or electronic storage of medical records, concern remains about the protection of such records by telemedicine providers, including security for the computer systems and other media on which they are stored.

Several reports indicate an absence of state-to-state uniformity in confidentiality and privacy laws that could have an adverse impact on the transfer of medical data for use in telemedicine encounters. One study by the Office of Technology Assessment expressed concern that a videotaped

⁵Annual Report to Congress, Physicians Payment Review Commission, 1995.

consultation that becomes part of a patient's medical record would be treated as the state treats other videotaped information on the patient.⁶ Because state laws governing the transmission and retrieval of patient medical records vary, officials are concerned about user verification, access, authentication, security, and data integrity.

Efforts are underway to (1) identify the privacy-related issues that arise particularly from the electronic environment of computerized records and network information systems and (2) recommend policies to address those issues. In March 1995, the Vice President asked HHS to lead efforts to develop model institutional privacy policies and model state laws for health information in the context of the National Information Infrastructure. An interdepartmental working group on privacy is currently identifying privacy issues related to transmission of health information and other issues involving electronic communications technology and integrated data systems. The group will make policy recommendation to address these issues. The results of their efforts are being discussed at JWGT meetings.

Safety and the Need for Policy on Medical Devices

FDA has responsibility for ensuring that medical devices are safe and effective and minimizing exposure from radiation-emitting electronic products. However, FDA has not clarified which telemedicine components fall within its definition of medical devices. Further, some of FDA's policies are out-of-date, particularly for computer software used in diagnosing patient conditions. Some manufacturers and others believe that these FDA policies and procedures have limited marketing of new products.

FDA's role has generated controversy in the telemedicine community. Some believe that telemedicine systems are medical devices in need of FDA review. Others believe that (1) these systems require FDA review no more than a telephone or fax machine used to communicate information used in patient diagnosis/treatment and (2) FDA regulation of telemedicine equipment may be unwarranted. In some instances, FDA's review process for medical devices is complicated and lengthy.

FDA's basis for regulating certain software as medical devices is contained in its 1987 draft guidance and a 1989 update. According to the Council on Competitiveness' March 1996 report, the review process for medical devices—which would also guide review of certain types of

⁶Bringing Health Care Online: The Role of Information Technologies, Office of Technology Assessment, 1995.

software—imposes an unworkable burden on software developers. In its July 1996 report to JWGT, FDA stated that major efforts are underway to define and develop software policy. The policy is expected to clarify the factors that determine which types of software are medical devices and the degree of regulatory scrutiny required.

As a first step in developing a policy, FDA conducted a forum in September 1996 to address its role in regulating software for clinical decision-making and proposed future directions related to software distribution issues, risk categories, and notification requirements. Further FDA efforts will be subject to comment by relevant public and private sector interests to ensure broad input into future decisions. As of November 1996, FDA had not yet revised its policy.

Financial Barriers

The lack of reimbursement for consulting physicians' services and the prohibitive high cost of telecommunication transmission services have deterred the expansion of telemedicine. Without good management plans to ensure future sources of funds, some telemedicine networks may not be sustained after federal funding subsidies lapse.

No Medicare Reimbursement of Providers

Currently, HCFA does not reimburse for telemedicine consultations for Medicare patients. One report indicated that HCFA's current position is one of the major obstacles to telemedicine's current use and future development.⁷ Fee-for-service providers who treat Medicare patients are affected by this obstacle, as well as those providers who are paid by insurers that follow HCFA's lead when deciding what costs to reimburse. HCFA is concerned that reimbursing consultant services via telemedicine could significantly increase expenditures from Medicare trust funds, which are already facing threats to their solvency.

A HCFA official stated that Medicare does not pay for telemedicine because it believes the standard practice of medicine requires an "in-person, face-to-face consultation" between the patient and practitioner for most medical specialties. In contrast, HCFA pays for telemedicine involving radiology and pathology because these specialties do not typically require face-to-face contact with the patient. HCFA also notes that with the exception of the American College of Radiology, the medical community has not developed practice guidelines for telemedicine.

⁷Rashid Bashshur, Dena Puskin, and John Silva. "Telemedicine and the National Information Infrastructure." *Telemedicine Journal*, Vol. 1, No. 4 (1995), p. 359.

In the area of Medicaid, a recent JWGT report indicates that at least 12 states now cover some aspect of telemedicine under Medicaid, and other Medicaid programs are pursuing coverage. Since Medicaid does not mandate a face-to-face encounter, a waiver is not needed for states to add telemedicine as an optional covered service.

In October 1996, HCFA announced that it will begin limited Medicare payments for telemedicine consultations in four states under a demonstration project. HCFA will evaluate those ongoing projects to (1) demonstrate the effectiveness of rural telemedicine systems and (2) develop, test, and evaluate payment methodologies for telemedicine consultations. Project evaluations are focused on the effects of telemedicine systems on accessibility, quality, and cost of health care. However, HCFA reports that until the analyses of the demonstration projects are completed, Medicare will not reimburse for video consults beyond the demonstration projects. Without proper research results and guidelines, HCFA, as well as other insurers, are concerned that reimbursement for these services will further increase the cost of medical services.

An official from a managed care organization agrees with HCFA's concern that increased access may result in increased utilization and thus increased cost. However, that official believes that expanded use of capitated managed care systems will enhance the appeal of telemedicine and reduce the need for HCFA reimbursement.

High Infrastructure Costs

Another frequently cited barrier to implementing telemedicine is lack of infrastructure in rural areas due to the prohibitive cost of running fiber optics or providing satellite, T-1, or Integrated Services Digital Network transmission service to a small end-user population. According to a 1995 HHS report, supporting the high fixed costs of maintaining a telecommunications infrastructure is clearly beyond the capability of small hospitals, particularly without subsidies or cost-sharing arrangements among multiple users.⁸ Small disparate rural telemedicine networks and other users do not have sufficient market power to negotiate favorable rates and service from telecommunications providers.

Some states, including Texas, have intervened and directed utility companies to limit charges to nonprofit health and education

⁸D.S. Puskin. "Opportunities and Challenges to Telemedicine in Rural America." *Journal of Medical Systems*, Vol. 19, No. 3, (1995), p. 59.

organizations. An official of one network told us that, after state intervention, the long distance carrier reduced its monthly charge for T-1 lines from \$2,500 to \$250 a month.

Our Georgia case study revealed that officials were concerned about the high costs of recurring line charges. VA, DOD, state, and private sector officials told us their recurring line charges ranged from \$1,100 to \$1,500 a month. In Georgia, the state temporarily subsidized line charges for remote sites on the state network. Some public officials, as well as private organizations within the state, worry that some smaller rural communities might have to close their centers once state funding is exhausted because they may not be able to afford the recurring monthly communication charge.

Universal service and advanced telecommunications service provisions of the Telecommunications Act of 1996 are intended to reduce costs in two ways. First, it will promote competition among local access and long-distance providers to make the National Information Infrastructure affordable and widespread. Therefore, a larger array of services may be available to select from at competitive prices. Second, the act will require utility companies to equalize rates between urban and rural users. Strategic partnerships between the health care industry and infrastructure providers may also speed the development of advanced telemedicine systems. The Federal Communications Commission is implementing these provisions of the act but has not made official recommendations in this area.

Local end users need a continuing source of revenue to support telemedicine programs once demonstration grant funds have lapsed, and some supporting programs have addressed that need. For example, the Department of Agriculture's Distance Learning and Medical Link Grant Program requires applicants to demonstrate local financial support by providing evidence that their projects will be self-sustaining. The Institute of Medicine's 1996 report acknowledges that few projects appeared to be guided by a business plan or the project features and results necessary for a sustainable program.⁹ In contrast, federal agencies are not required to earn a profit on their telemedicine networks, but substantial usage is necessary to achieve their goals of access to quality care.

⁹Telemedicine: A Guide to Assessing Telecommunications in Health Care, Institute of Medicine, National Academy of Sciences, 1996.

The Council on Competitiveness' March 1996 report points out that those who do not have access or have limited access to quality care may stand to benefit the most from telemedicine, but they also may be the least able to pay for these services. Without some payment support mechanism, infrastructure or health care providers may not consider telemedicine alone to be capable of delivering a sufficient return to justify their investment. However, if multiple applications are available to use the infrastructure, such as those related to education or entertainment, the infrastructure costs can be shared, and the overall return on investment can be increased.

Technical Barriers

The lack of clinical and technical standards for transmitting data is a major inhibitor to networking information systems. Many agencies and organizations will need to work together to resolve this problem. Radiology is the only medical specialty to develop technical standards, which are still being revised. Also, federal and other users experienced another barrier—difficulties with telemedicine equipment compatibility. Many challenges will be encountered in overcoming this obstacle.

Slow Development of Standards

Another issue complicating telemedicine is the general lack of standards. These standards relate to data definitions, coding or content, and transmission of diagnostic images (e.g., speed, resolution, and image size). The general lack of documented record formatting standards has been a major inhibitor to networking information systems within and across managed care organizations and for other players in the health care system. Today, much of the data content exchanged, such as the patient's relationship to the member, is left to the interpretation of individual managed care organizations; providers must make assumptions when coding claim data elements and frequently use coding standards employed by the provider's system. According to our 1993 and 1994 reports, these distinctions are very important to the payor and provider, since they can affect which insurance company will be liable for a claim.¹⁰ Also, the Council on Competitiveness' March 1996 report states that data requirements should be clearly articulated by health care entities, including (1) definitions of the data they need, (2) the format in which they expect to receive such data, (3) the way in which data should be submitted (e.g., electronically), and (4) the frequency with which data should be submitted.

¹⁰Health Care: Benefits and Barriers to Automated Medical Records (GAO/T-AIMD-94-117, May 6, 1994) and Automated Medical Records: Leadership Needed to Expedite Standards Development (GAO/IMTEC-93-17, Apr. 30, 1993).

The standard that allows formatting and exchanging of images and associated information is known as the Digital Imaging and Communications in Medicine. This standard was developed by the American College of Radiology, the first to publish standards for any application for telemedicine, and the National Electrical Manufacturers Association, which represents companies that manufacture medical equipment. Numerous government agencies and other national organizations are involved in the health care information standards process.¹¹ A number of other medical specialty organizations are working on standards for clinical practice for their profession, such as the American Academy of Dermatology and American College of Cardiology.

Technology and Equipment Incompatibility

Technology limitations, as well as equipment incompatibility, present challenges for both the public and private sectors. To successfully implement telemedicine within the framework of the National Information Infrastructure, interconnectivity and interoperability of multiple systems need to be ensured.¹² For example, after purchasing one manufacturer's telecommunication system, an Alabama VA hospital learned that its equipment could not fully interface with another manufacturer's equipment purchased by another VA hospital. Worried that this incompatibility problem could surface again, one of the VA's Veteran's Integrated Service Network offices appointed a special committee to handle the procurement needs for all facilities in Alabama. As health care providers increase use of telemedicine, they will face increased challenges to coordinate equipment, hardware, and software components.

The military has also experienced equipment incompatibility problems. In 1994 and 1995, the battle lab at Fort Gordon, Georgia, sponsored a Joint Warfighter Interoperability Demonstration in which industry, academia, and others were given an opportunity to demonstrate medical communication products with war-fighter applicability. Several officials associated with the demonstration told us that, during the exercises, some demonstrations were less than successful due to equipment incompatibility. In one demonstration, the Army found that its telemedicine equipment was not compatible with other Army command, control, and communication systems. In another exercise, a joint service

¹¹The Council on Competitiveness' March 1996 report lists 31 agencies or organizations involved in the process of setting standards.

¹²Interoperability refers to the ability of different components within a single as well as different telemedicine systems to interact with each other without having to overcome considerable technological barriers.

demonstration failed because one service's medical communications equipment could not "talk" to the others. From the perspective of the Army Signal Corps community, these sorts of impediments could pose serious problems on the battlefield. The Director of Combat Developments at Fort Gordon stated that, during an armed conflict, the Signal Corps assumes command and control over all communication systems, including medical communications. The Signal Corps worries that telemedicine equipment brought to the front will not be able to successfully integrate with the established battlefield communication infrastructures and therefore not be functional during a conflict.

Also, the emphasis placed on high-technology systems without sufficient consideration of the specific clinical and health care requirements and infrastructure capabilities in each setting has created a poor fit between telemedicine system design and end-user needs. Given the constraints on financial resources in most communities in need of telemedicine services, every effort should be made to design scaleable systems that can serve the immediate and essential clinical and health care needs at minimal cost. Upgrading can follow as further needs are identified and the financial capabilities of communities increase. As the technology expands and the cost of equipment becomes more competitive, telemedicine systems will be able to increase their technical capabilities.¹³

DOD's Unique Telemedicine Challenges

In discussing telemedicine and deployed scenarios with service officials, we learned of circumstances that present unique challenges for the military. Traditionally, communications within the military have been used to enable command and control. Telemedicine requires communications that are provided in a functional manner and cross lines of command. In addition to new linkages, more sophisticated telemedicine technologies require the transmission of image data, which places considerable demands on bandwidth communications.

DOD does not have a dedicated medical communications network. Therefore, telemedicine communications transmissions have to compete with other critical transmissions. In time of war, these requests could be for enemy coordinates or attack and defend commands. An Army official stated that if a medical facility used a secure military satellite to transmit medical information to and from the battlefield during an armed conflict, that facility would lose its neutral zone classification. Under the Geneva

¹³Rashid Bashshur, Dena Puskin, and John Silva. "Telemedicine and the National Information Infrastructure." *Telemedicine Journal*, Vol. 1, No. 4 (1995), p. 349.

Rules of Conduct for Warfare, the enemy can engage any facility transmitting communication data over secured lines. This rule makes medical facilities in theater, normally protected from attack, open to enemy assault.

Today, the combat medic does not have adequate means for video communication, and military medical treatment facilities have limited bandwidth available for telemedicine communications, both within the theater of operations and with connections to the sustaining base. Further, the Navy has an extremely challenging problem, since all data used must be transmitted and received using data links that are already used to capacity on most ships. Navy ships are deployed every day, regardless of national security posture.

Our study revealed that military personnel are concerned about technical limitations associated with size and weight in relation to deploying telemedicine to the battlefield. For example, the Army's prototype battlefield telemedicine unit in Bosnia, the Deployable Telepresence Unit, weighs about 3 tons and takes up about 400 square feet of space. Until the unit's size and weight constraints can be overcome, advancing telemedicine to the front, where the majority of casualties occur, is not feasible.

The Army is currently using data communications provided by the Defense Information Systems Agency for both Primetime III deployment to Hungary and Bosnia as well as peacetime regional telemedicine in Region 6 (Fort Hood, Brooke Army Medical Center, and Wilford Hall Air Force Medical Center). This agency is leasing commercial circuits. Future telemedicine requirements supported by this agency will be provided to the services as part of the agency's Global Combat Service Support System, which is the unclassified part of the Global Command and Control System. According to Army Medical Command officials, the Warfighter Information Network, which embraces developing technologies, such as asynchronous transfer mode, fiber optic connectivity, and personal communications system cell phones, is expected to satisfy telemedicine bandwidth requirements on the battlefield and provide the needed link to the combat medic serving the combat arms.

Cultural Barriers

Cultural barriers must be overcome to sustain telemedicine networks with little usage after government subsidies lapse. These barriers fall into two categories: physician acceptance (which includes their discomfort with

using high-technology equipment and their skepticism about diagnosing and treating patients at a distance) and patient satisfaction with using telemedicine.

Physician Acceptance of Telemedicine

One way to increase utilization of telemedicine networks is to foster higher physician acceptance. Some telemedicine projects that experienced high usage have factors that may help other users. For example, officials from the Texas Department of Corrections believe they have alleviated physician acceptance concerns through the following actions: (1) caregivers from referring facilities visit the consulting physicians to discuss how consultations should be conducted; (2) technicians at both ends of the consultation operate the telecommunications equipment, thus freeing caregivers to perform clinical procedures; and (3) consultants seek clinicians' advice on how to provide better care to patients. The findings of the Texas study are supported by the 1995 annual report to Congress by the Physicians' Payment Review Commission, which concluded that physician acceptance issues may become less important as physicians gain experience and familiarity with telemedicine services.

However, physician acceptance continues to be an issue, according to expert opinion and our data. According to an American Medical News article, among the many obstacles facing telemedicine, proponents say "people issues" worry them the most.¹⁴ Literature reveals that the reluctance of physicians to use telemedicine services may be influenced by their attitudes about quality, control of patient care and referral relationships, convenience, and fear that urban medical centers would steal rural patients. For example, some uninterested doctors reported scheduling difficulties, inability to actually examine patients, and unfamiliarity with the technology as reasons that have deterred them from participating in telemedicine activities.

During our Georgia case study, various telemedicine officials often spoke about resistance to change. In one instance, medical personnel at a military clinic stated they were reluctant to use the teleradiology system primarily because they preferred having a radiologist on hand that they knew, trusted, and could rely on. In addition, the radiologists at the consulting facility were occasionally slow to respond to requests for consultations. Some physician resistance is due in part to the relative complexity of the systems currently in use. The equipment is not

¹⁴"Telemedicine Coming of Age: Friend or Foe? Rural Doctors Unsure." *American Medical News*, April 1995.

user-friendly; therefore, additional training is required to learn how to operate the equipment. Some VA telemedicine projects have also experienced low utilization because of physician reluctance.

A 1995 journal article by HHS and the Telemedicine Center, Medical College of Georgia, states that the designs of current systems are driven more by technology than by the needs of physicians.¹⁵ To be successful, the article noted that telemedicine technologies may need to adapt to the needs of physicians and patients, not vice versa. Training was cited as a key component of any successful telemedicine system to help physicians with limited experience and comfort with computers. A June 1994 report of the Council on Medical Service, part of the American Medical Association, cited a need for physician education as it relates to instruction covering the spectrum from basic computer literacy to familiarity with expert diagnostic systems and knowledge databases. The association's policy recommends that designers of clinical information systems involve physicians in all phases of system design and select technologies that are easily mastered, flexible, and acceptable to physician users.

Patient Acceptance of Telemedicine

Patient acceptance with using telemedicine for consultations may be less of a barrier than physician acceptance, particularly in rural settings. A few limited patient satisfaction surveys found that the convenience of not needing to drive hundreds of miles to an appointment with a specialist outweighs any uneasiness of not seeing that specialist face to face. According to one researcher, patients in South Dakota and Florida have uniformly shown acceptance to telemedicine. An evaluation of the Texas criminal justice telemedicine project found that about 70 percent of the patients preferred telemedicine consultations to transportation to the tertiary care hospital and another 14 percent were neutral.

A project sponsored by the University of Kansas found that patients were happy not to have to drive 300 or 400 miles just to see their physician. They also appreciated receiving a videotape of their visits. On the negative side, the Kansas patients found being candid on video to be difficult and were not eager to repeat their experiences.

¹⁵Dena Puskin and Jay Sanders. "Telemedicine Infrastructure Development." Journal of Medical Systems, Vol. 19, No. 2 (1995), p. 127.

Agency Comments

In commenting on a draft of this report, HHS said that a clearer depiction of the role of FDA in telemedicine was needed. Accordingly, we clarified this information.

Conclusions and Recommendations

Conclusions

Telemedicine has the potential to revolutionize the way health care is delivered. The recent increased interest in telemedicine technology has resulted in widespread applications throughout the United States. Collectively, DOD, other federal agencies, state governments, and the private sector have already invested hundreds of millions of dollars on numerous telemedicine projects, sometimes in collaboration with each other. However, it is impossible to determine the full scope of these initiatives. They range from long-term research efforts exploring robotic or telepresence surgery to pilot programs at medical facilities where some clinical application, such as teledentistry, is actually practiced. The most common current clinical application is teleradiology.

DOD and other federal agencies are actively sponsoring telemedicine projects that individually seem justifiable and fall under the purview of the sponsoring agency's mission. However, not enough comprehensive, accurate information exists to determine the collective value of these projects. For example, it is difficult to tell whether DOD's investment is commensurate with the potential benefits it stands to gain. DOD is currently the largest federal investor with \$262 million. On a case-by-case basis, many projects seem justifiable, but the collective value of the DOD telemedicine program cannot be easily assessed. In fact, DOD's telemedicine program is actually the sum of many individual parts and not an interrelated group of projects prioritized to accomplish specific goals. Some agencies, including DOD and VA, have recognized the need for a telemedicine strategy to define their programs but have not moved beyond the conceptual stage. Private sector organizations are reluctant to share their market observations and data for fear of revealing helpful information to their competition. Further, because priorities differ among the public and private sectors, working together is even more difficult without clear and common goals.

Successful expansion and sustainment of telemedicine will require resolution of many legal and regulatory, financial, technical, and cultural barriers. Some of the more critical barriers, such as licensure, privacy, and infrastructure costs, are too broad and have implications too far-reaching for any single sector to address. On the other hand, some barriers, such as physician acceptance, can be overcome at the local level with proper planning and management. Because federal agencies that directly deliver health care, such as DOD, VA, IHS, and BOP, are less affected by licensure and reimbursement barriers, they are better placed to provide comprehensive information to help determine the course of telemedicine.

The numerous telemedicine initiatives funded by the public and private sectors could be more productive if they were linked by common goals, such as interdependent utilization of the information superhighway to provide cost-effective and quality health care. Such a goal should complement, not supplant, individual missions, such as improving rural or remote health care delivery, by serving as a vehicle for sharing technical progress and avoiding duplication. The challenge is how to find such a link without impeding progress of an emerging technology so difficult to define.

Recommendations

By nature, telemedicine issues cut across public and private sectors and across agencies within the federal sector. Although there is a need to develop national goals and objectives to guide federal telemedicine investments, it would be difficult for an individual department or agency to be the architect of a governmentwide strategy. JWGT is already performing some interagency coordination associated with carrying out the Vice President's charge to the Secretary of HHS to prepare a comprehensive report on telemedicine issues. Therefore, JWGT is in a good position to expand its work and take the lead in proposing a coordinated federal approach for investing in telemedicine. Such efforts should provide a framework to optimize the value of federal telemedicine investments with activities sponsored by the states and private sector.

Accordingly, we recommend that the Vice President direct JWGT, in consultation with the heads of federal departments and agencies that sponsor telemedicine projects, to propose a federal strategy that would establish near- and long-term national goals and objectives to ensure the cost-effective development and use of telemedicine. In addition, the proposed strategy should include approaches and actions needed to

- establish a means to formally exchange information or technology among the federal government, state organizations, and private sector;
- foster collaborative partnerships to take advantage of other telemedicine investments;
- identify needed technologies that are not being developed by the public or private sector;
- promote interoperable system designs that would enable telemedicine technologies to be compatible, regardless of where they are developed;
- encourage adoption of appropriate standardized medical records and data systems so that information may be exchanged among sectors;
- overcome barriers so that investments can lead to better health care; and

- encourage federal agencies and departments to develop and implement individual strategic plans to support national goals and objectives.

Further, because DOD is the major federal telemedicine investor and manages one of the nation's largest health care systems, it is in a good position to help forge an overall telemedicine strategy. A first step is to develop a departmentwide strategy. Therefore, we recommend that the Secretary of Defense develop and submit to the Congress by February 14, 1998, an overarching telemedicine research and development and operational strategy. The strategy should

- clearly define the scope of telemedicine in DOD;
- establish DOD-wide goals and objectives and identify actions and appropriate milestones for achieving them;
- prioritize and target near- and long-term investments, especially for goals related to combat casualty care and operations other than war; and
- clarify roles of DOD oversight organizations.

Agency Comments and Our Evaluation

We provided a draft of this report to DOD, VA, HHS, and the Office of the Vice President. Both DOD and VA concurred with our recommendations. DOD stated that it "... is not alone in finding itself behind the technological bow wave of telemedicine" (see app. III). DOD said that one of its first priorities will be the development of a definition and scope of DOD telemedicine activities. DOD also agreed to establish departmentwide goals and objectives and prioritize investments as part of its strategic telemedicine plan. According to DOD, many pieces of this plan are already in place. VA commented that it would be beneficial for DOD to include VA in its development of an operational strategy for telemedicine activities (see app. IV).

After subsequent discussions with HHS officials regarding agency comments, HHS generally agreed with the concept of our recommendation for JWGT to play a leadership role in proposing national goals and objectives (see app. V). HHS was concerned that a governmentwide strategy could be overly prescriptive. Our recommendation was not intended to imply that JWGT direct federal agencies investments in telemedicine initiatives but rather that JWGT develop a roadmap for federal agencies to use as a guide for their investments. HHS also stated that it might be better to require individual departments to develop their own strategies before an overarching federal strategy is proposed. We believe that individual strategies should be developed but that these strategies

would not ensure an interagency commitment to common goals and objectives or serve as a guide to prevent duplicative investment efforts. We further believe that some agencies, such as DOD and VA, might be in a better position than others to move forward with individual strategies, whereas other agencies would benefit from an overall federal plan to help develop their individual strategies.

HHS commented that JWGT had accomplished much of what we were recommending. We believe that JWGT should be commended for its efforts toward fulfilling the reporting requirements to the Vice President and the Congress. Many indirect benefits toward informal coordination of federal telemedicine activities are occurring. However, drafts of JWGT reports to the Vice President and the Congress provided to us do not reflect a proposal for the type of governmentwide strategy we are recommending for agencies to maximize their telemedicine investments. Rather, these draft reports mostly reflect information on issues to be pursued related to barriers, such as physician licensure, that may prevent the widespread application of telemedicine.

Our draft report recommended that JWGT membership be expanded to include private and state representation. HHS expressed concerns about implementing this portion of the recommendation due to requirements in the Federal Advisory Committee Act.¹ According to HHS, the act would require reimbursement for expenses of any state or private sector representative to attend the group's bimonthly meetings and could otherwise impair JWGT's operations. As an alternative, HHS suggested the addition of an annual telemedicine summit with state and private participation to JWGT's activities. We believe the specific vehicle chosen is not important as long as it improves the interaction of federal, state, and private sectors along the lines noted in our recommendations. Accordingly, we modified our recommendation by deleting suggestions to expand JWGT beyond federal agency membership. For the same reasons, the merits of HHS' proposal for an annual summit—certainly a constructive step—would have to be judged against the summit's ability to foster the actions sought by our recommendation. We believe that JWGT should have the flexibility to make this determination.

Within the Office of the Vice President, the Chief Domestic Policy Advisor and the Senior Director for the National Economic Council did not provide us with written comments. The Senior Director for the National Economic Council, however, raised questions regarding the impact of the Federal

¹5 USCA App. 2 Section 1 et seq.

Chapter 6
Conclusions and Recommendations

Advisory Committee Act on expanding the membership of JWGT to include state and private membership. Further, DOD and HHS provided specific technical clarifications that we incorporated in the report as appropriate.

Organizations Visited

Federal Departments and Independent Agencies

Appalachian Regional Commission

| | |
|--|---|
| Department of Agriculture | Rural Utilities Service |
| Department of Commerce | National Telecommunications and Information Administration National Institute of Standards and Technology, Advanced Technology Program |
| Department of Defense | Office of the Assistant Secretary for Health Affairs Air Force Surgeon General Army Surgeon General Navy Surgeon General Army Medical Department Medical Advanced Technology Management Office Portsmouth Naval Medical Center Wilford Hall Air Force Medical Center Madigan Army Medical Center Tripler Regional Medical Center Brooke Army Medical Center Walter Reed Army Medical Center National Naval Medical Center Bethesda Naval Hospital Camp Lejeune Armed Forces Institute of Pathology Defense Advanced Research Projects Agency |
| Department of Health and Human Services | Food and Drug Administration Health Care Financing Administration Agency for Health Care Policy and Research Indian Health Service |

Appendix I
Organizations Visited

National Institutes of Health, National Library of Medicine
Health Resources and Services Administration, Office of Rural
Health Policy

Department of Justice

Bureau of Prisons

**Department of Veterans
Affairs**

Veterans Health Administration

**National Aeronautics and
Space Administration**

**National Science
Foundation**

State Governments

Georgia
Texas

**U.S. Health Care
Organizations**

American Academy of Dermatology
American Academy of Family Physicians
American Medical Association
Federation of State Medical Boards
American College of Cardiology
American College of Emergency Physicians
American College of Pathologists
American College of Radiology
American College of Surgeons
National Council of State Boards of Nursing
American Dental Association

**Other Private U.S.
Organizations**

Council on Competitiveness
National Electrical Manufacturers Association
National Academy of Sciences, Institute of Medicine
American Telephone and Telegraph
The Koop Foundation
Center for Public Service Communications
Computer Motion, Inc.

Appendix I
Organizations Visited

Western Governors Association
Allina Health Systems
Mayo Clinic

Academia

George Washington University, Intergovernmental Health Policy Project
University of Washington School of Medicine
East Carolina University

**Organizations Within
Georgia**

Department of Defense

Dwight David Eisenhower Army Medical Center, Fort Gordon
Center for Total Access, Southeast Telemedicine Testbed, Fort Gordon
Tingay Dental Clinic, Fort Gordon
U.S. Army Signal Center, Fort Gordon
U.S. Army Health Clinic, Fort McPherson
U.S. Army Dental Clinic Command, Fort McPherson

**Department of Veterans
Affairs**

Decatur Medical Center
Augusta Medical Center

State Agencies

Department of Administrative Services
Department of Human Resources
 Office of Rural Health and Primary Care
 Child and Adolescent Health Unit, Division of Public Health
Department of Corrections

Academia

Center for Telemedicine, Medical College of Georgia
Robert W. Woodruff Health Sciences Center, Emory University
Biomedical Interactive Technology Center, Georgia Institute of
 Technology

Appendix I
Organizations Visited

Private Organizations

Georgia Baptist Hospital
The Marcus Center at Emory University
Egelston Hospital for Children, The Children's Heart Center
Scottish Rite Children's Medical Center
American Telephone and Telegraph
Panasonic
Bell South Foundation
The Georgia Power Foundation
Medasys Digital Systems

Telemedicine Initiatives Within the Department of Defense and Other Federal Agencies

Federal departments and agencies have invested in a range of telemedicine projects. This appendix describes some of the key projects funded during fiscal years 1994-96 by the Department of Defense (DOD) and the following eight federal civilian agencies: the Departments of Veterans Affairs (VA), Health and Human Services (HHS), Commerce, Agriculture, and Justice; National Aeronautics and Space Administration (NASA); National Science Foundation, and Appalachian Regional Commission.

DOD Is the Largest Single Federal Investor

DOD has invested \$262 million in telemedicine initiatives over the last 3 fiscal years. As table II.1 shows, DARPA has invested the most in telemedicine projects in fiscal years 1994-96, followed by the Army (after excluding amounts spent on congressionally directed programs). These investments cover both battlefield and peacetime health care.

Table II.1: Telemedicine Investments by DOD Organizations, Fiscal Years 1994-96

| Dollars in millions | | | | |
|---------------------|---------------|----------------|----------------|----------------------------|
| Organization | FY 94 | FY 95 | FY 96 | Total |
| DARPA | \$20.3 | \$43.3 | \$41.0 | \$104.6 |
| Army | 15.2 | 51.0 | 60.0 | 126.2 ^a |
| Navy | 0.1 | 8.5 | 10.5 | 19.1 |
| Air Force | 1.5 | 3.7 | 6.8 | 12.0 |
| Total | \$37.1 | \$106.5 | \$118.3 | \$261.9^a |

Note: Funds provided by Health Affairs are included in the services' investments.

^aThese amounts include \$58.4 million in congressionally directed programs.

DARPA Focuses on Unique Battlefield Applications

Since 1994, DARPA has invested \$104.6 million in 24 telemedicine research and development projects. DARPA's objective is to provide medical care as far forward on the battlefield as possible. Although DARPA attempts to obtain private sector cost-sharing arrangements when feasible, it can be difficult to obtain such arrangements early in the research and development stage, since industry has a short-term immediate payoff perspective. According to DARPA officials, its 24 projects have resulted in 86 contract awards or partnership agreements with industry and academia participants. Some examples of DARPA's key projects follow.

- In partnership with the Applied Physics Laboratory at the University of Washington and Bothwell's Advanced Technology Laboratories, DARPA is developing a hand-held ultrasound device for medics to use on the

battlefield. The device, weighing from 2 to 4 pounds, will transmit real-time radiology images over communication lines to a mobile Army surgical hospital unit.

- DARPA's soldier physiologic monitor is a hand-held device that will help the combat medic locate a wounded soldier and monitor the soldier's vital signs (i.e., body temperature, heart rate, breathing rate, and blood pressure). Prototypes of the physiologic monitor are currently being tested and evaluated by the Army ranger school.
- DARPA's Life Support for Trauma and Transport, or "Smart Litters," will provide built-in patient monitoring and telemetry as well as life support enhancements. This project is an intensive care cocoon, which will provide monitoring, environmental control, oxygen generation, data logging and access, and ventilator support in a sealed environment. The goal is to lengthen the golden hour (the first hour after a soldier is wounded) of medical care by providing critical care stabilization. The survivability of a wounded soldier is greatly enhanced when treated and stabilized within the golden hour.
- DARPA also has a joint project with the Georgia Institute of Technology and the Medical College of Georgia to develop a tactile sensing glove. The goal is to develop a system for allowing the specialist to palpate a patient at a remote site. For example, the consulting physician should be able to feel a mass in the remote patient's abdomen.

Army Has Battlefield and Peacetime Telemedicine Initiatives

The Army has invested \$126.2 million in telemedicine since fiscal year 1994. These investments include approximately \$46.7 million that the Medical Advanced Technology Management Office (MATMO) oversees, \$58.4 million for specific projects directed by Congress, and \$21.1 million for other peacetime health care initiatives.

MATMO, part of the Army Medical Research and Materiel Command, has sponsored 21 telemedicine projects, some of which focus on battlefield health care. For example, MediTag is a wearable dog tag-like device that allows the electronic storage of medical information on the battlefield.

Other Army organizations sponsor projects to build medical networks in various medical treatment facilities. These projects are mostly related to telemedicine initiatives at U.S. Army medical centers. For example, Walter Reed Army Medical Center in Washington, D.C., initiated medical information networks at its various medical treatment facilities to provide telemedicine conferencing capability for dermatology and orthopedic consultations, distance learning, and imaging support for dental activities.

Appendix II
Telemedicine Initiatives Within the
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Brooke Army Medical Center in Texas established a telemedicine connection with Darnall Army Community Hospital that allows specialists at the center to interact with hospital patients in clinical specialties of obstetrics and gynecology, radiology, cardiology, pediatrics, internal medicine, psychiatry, and nursing education. Also, collaborative efforts between Brooke Army Medical Center and the Air Force's Wilford Hall Medical Center in San Antonio, Texas, are supporting clinical consultations for TRICARE Region 6 and the Bosnia deployment.

In addition, Congress has mandated several telemedicine projects targeted to improve management of medical information in Army military treatment facilities in Hawaii, Washington, and North Carolina. These projects are funded outside DOD's budget request and during fiscal years 1994-96 totaled \$58.4 million.

Two projects—Akamai and the Pacific Medical Network—are based at Tripler Regional Medical Center in Honolulu, Hawaii. The projects are designed to provide health care throughout the Pacific Basin by using various telemedicine technologies. Akamai is designed to expand access of the Medical Digital Imaging Support (MDIS) system and other telemedicine applications. Akamai funding for fiscal years 1994-96 was \$31 million.¹ Of these funds, about \$18 million was spent on telemedicine projects (about \$13 million for MDIS and the remaining funds for clinical diagnosis and consultations, administrative, and evaluations) at Tripler. Of the remainder, Georgetown University received about \$9 million, DARPA received about \$1.7 million for the soldier physiologic monitor, and Health Affairs and MATMO used almost \$2 million.

The Pacific Medical Network is a prototype effort designed to create a computer-based patient record that can be transmitted across great distances and multiple time zones. Several projects, when combined, are expected to provide the capability to move critical patient data, such as digital x-rays and medical history (including hospital stays, outpatient visits, laboratory results, and immunizations), between treatment facilities as patients are transferred from one facility to another.

Another congressional project, known as Seahawk, is based at Madigan Army Medical Center in Tacoma, Washington, and designed to implement MDIS and teleradiology and other telemedicine applications within the Puget Sound urban environment. The network will include all Army, Navy,

¹A March 1996 audit report by Booz-Allen and Hamilton, Inc., Akamai Financial Rebaseline Analysis Report, was issued at the request of Tripler officials on these appropriated funds.

Air Force, and VA medical facilities in the area. Congressional funding was \$6.9 million for fiscal years 1995 and 1996. In fiscal year 1996, Health Affairs provided additional funding of \$4.8 million.

The Walter Reed Army Medical Center is completing a 3-year congressionally appropriated project with the Carolina Medical Center in Charlotte, North Carolina. The two institutions received almost \$3 million to evaluate desktop telemedicine. Walter Reed's expenditures included about \$40,000 for computers and associated hardware to be used at Fort Bragg, North Carolina; Fort Belvoir, Virginia; and the National Naval Medical Center, Bethesda, Maryland.

**Navy Has Focused on
Connectivity With Ships**

For fiscal years 1994 through 1996, the Navy funded 21 pilot projects by reprogramming efforts at a cost of \$19.1 million. The Navy's strategy has been directed mostly at establishing connectivity on deployed ships with naval medical facilities based in the continental United States. For example, telemedicine has been used during training exercises on selected medical facilities afloat (i.e., the U.S.S. George Washington and the U.S.S. Abraham Lincoln). The Navy expects to integrate lessons learned from these experiences into ships that have not yet received communications connectivity.

The Navy Bureau of Medicine and Surgery has identified about \$900 million for future telemedicine initiatives that involve communications connectivity between deployed ships and naval medical facilities and connections between shore-based tertiary medical facilities and outlying clinics. Although the Navy requested funds for these initiatives in the fiscal year 1997 Program Objective Memorandum, DOD officials said that the climate of funding constraints precluded further consideration of the requests.

**Air Force Efforts Focus on
Peacetime Care**

Air Force officials stated that, because both peacetime and contingency operations use the same telemedicine applications, experience gained from day-to-day peacetime initiatives can later be applied to contingency operations. During fiscal years 1994-96, the Air Force had three ongoing telemedicine demonstrations. These projects were funded at a cost of \$10.5 million from then-year operation and maintenance funds.

The most significant Air Force telemedicine effort is taking place at Wilford Hall Medical Center. This pilot project, in which the Air Force is

acting as DOD's TRICARE lead agent, is expected to introduce telemedicine into the daily practice and training for health care providers in TRICARE Region 6. This region includes one Army medical center and three hospitals; one Air Force medical center, eight hospitals, and five clinics; and one Navy hospital and three branch clinics. According to the Office of the Air Force Surgeon General, the project strategies developed in Region 6 will act as a model for future regions in which the lead agent is an Air Force medical center.

As of May 1996, the pilot project was in its early operational stage. The project is expected to be phased in over 1 to 2 years to help ensure the transition from current medical practices to clinical telemedicine applications. The initial stage will be a demonstration testbed for teleconsultation and teleradiology on a small scale. According to the telemedicine project director, this demonstration will provide the opportunity to evaluate administrative procedures and technological applications and make any necessary improvements before full implementation of the project throughout the region.

Non-DOD Federal Investments Include a Wide Range of Projects

Eight other federal departments and independent agencies have invested in telemedicine initiatives that are consistent with their overall agency responsibilities. From fiscal years 1994 to 1996, these agencies invested \$384 million to deliver health care, sponsor telecommunications development, and evaluate the effectiveness of telemedicine systems.

VA Focuses on Telemedicine Infrastructure

VA's 159 medical centers use several forms of telemedicine to help deliver health care to its beneficiaries. VA officials estimate their cost to acquire the equipment and telecommunications lines was \$142 million for fiscal years 1994 through 1996. Many of these activities were initiated at the center level, although VA conducts some national projects. For example, the Baltimore Medical Center has fully digitized its x-rays and magnetic resonance images. Storing all such images on computer produces better images, allows several users to view them simultaneously, and eliminates cost and disposal problems associated with camera film.

Two VA medical centers, Washington and San Francisco, routinely review the status of cardiac pacemakers worn by VA patients. By reviewing electronic signals via telephone lines, VA staff can determine if a pacemaker needs to be replaced. This review reduces the number of unnecessary operations to replace pacemakers. The VA medical center

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near Atlanta uses its telemedicine system for continuing medical education and training residents. The center receives weekly epidemiology classes from the Centers for Disease Control and Prevention.

HHS Invests in a Wide
Array of Telemedicine
Initiatives

HHS spent an estimated \$110 million for telemedicine in fiscal years 1994-96 on a variety of telemedicine activities that reflect the missions of five of its agencies, as table II.2 shows. Many of these grants focused on rural or remote health care delivery.

Table II.2: Telemedicine Investments
for HHS Agencies From Fiscal Years
1994 to 1996

| Agency within HHS | Primary mission | FY 94 | FY 95 | FY 96 | Total |
|--|------------------------|---------------|---------------|---------------|----------------|
| National Library of Medicine | Research | \$27.7 | \$0.9 | \$40.0 | \$68.7 |
| Office of Rural Health Policy | Clinical health care | 6.9 | 7.6 | 10.1 | 24.7 |
| Agency for Health Care Policy and Research | Research | 0.7 | 5.5 | 1.9 | 8.2 |
| Health Care Financing Administration | Evaluation | 4.0 | 0.5 | 3.5 | 8.1 |
| Indian Health Service | Clinical | 0.1 | 0.1 | 0.2 | 0.3 |
| Total | | \$39.5 | \$14.6 | \$55.8 | \$109.9 |

Note: Figures do not add due to rounding.

The National Library of Medicine was the largest HHS investor (\$68.7 million) for fiscal years 1994 through 1996. Most of this agency's investments support research into biomedical applications of high-performance computing and communications that could evaluate the impact of telemedicine on health care access, quality, and cost for a wide variety of patients. For example, one contract with a private firm and the University of Maryland at Baltimore will investigate the feasibility of transmitting real-time vital sign data and video images of ambulance patients to hospital emergency room staff.

As the second largest investor, the Office of Rural Health Policy provided \$24.7 million in grants to private organizations to facilitate development of rural health care telemedicine networks. One grant to the Eastern Montana Telemedicine Network links a tertiary care hospital in Billings to

eight community health centers in isolated rural areas to provide mental health consultations. A contract with Abt Associates funded a survey of rural hospitals to determine how hospitals were using telemedicine. The study concluded that teleradiology was used most frequently but that usage was very low.

The Agency for Health Care Policy and Research (\$8.2 million) supports research and evaluation or cost-effectiveness studies into improving the collection, storage, and dissemination of health information, such as patient records and clinical decision support systems. For example, the agency contracted with the University of Washington to develop health care information and communication systems policy options for state governments to increase access and effectiveness of basic health services.

The Health Care Financing Administration awarded \$8.1 million to demonstrate and evaluate the cost-effectiveness of telemedicine systems, especially regarding payment methodology for telemedicine consultations. These funds support contractors who are evaluating the costs and benefits of telemedicine networks located in remote areas of Georgia, Iowa, North Carolina, and West Virginia.

The Indian Health Service spent about \$0.3 million for telemedicine equipment and infrastructure for its clients on remote reservations and small communities in Alaska, Arizona, New Mexico, and Oregon. For example, the agency's largest project placed radiographic readers in 10 hospitals and clinics on the Navajo Reservation. X-rays are scanned and transmitted to other Navajo area hospitals or the University of New Mexico Medical Center where consulting radiologists can provide a diagnostic report.

Although the Food and Drug Administration (FDA) does not invest directly in telemedicine, it conducts in-house research into emerging technologies to evaluate their potential public health impact. It also conducts research into problems with existing products and technologies that may affect public health. FDA ensures that medical devices are safe and effective by establishing safety standards and approving the manufacture and distribution of medical devices. It does not fund efforts for device development. Examples of medical devices used in telemedicine that fall under FDA's authority include radiological imaging, transmission equipment that utilizes data compression, and software for computer-assisted medical diagnosis.

Commerce Assists Private Sector Development of Advanced Technology

For fiscal years 1994 through 1996, the Department of Commerce spent about \$106 million on two programs that include telemedicine among the developing technologies they support. The National Institute of Standards and Technology operates the Advanced Technology Program (\$93 million), which supports research into improvements in health information management. For example, one 1995 cooperative agreement with a private firm will develop a voice-activated computer system to periodically monitor homebound patients and automatically notify a physician if problems are detected.

The National Telecommunications and Information Administration operates a program (\$12.9 million) that grants funds to acquire personnel, training, equipment, and services to demonstrate the use of advanced telecommunications in health. One award in 1995 was to Hays Medical Center in Kansas, which is using cable television facilities to provide home health care to remote elderly patients. Home health care aides in a rural area use the system to make interactive video "house calls" to homebound patients. Each day, a home health aide and a patient meet for an interactive videoconference. The aide talks with the patient, observes the patient's condition, and has the patient transmit medical data, such as blood pressure or glucose level, over the cable system. By saving the significant travel time associated with driving from one home to another, the project allows home health aides to see more patients, enabling more people to stay at home instead of being transferred to nursing homes.

Agriculture

The Rural Utilities Service within the Department of Agriculture administers the Distant Learning and Telemedicine Grant Program. This program is designed to encourage, improve, and make affordable the use of telecommunications, computer systems, and related technology for rural communities to improve access to education or medical services. During fiscal years 1994 through 1996, this program awarded \$9.3 million for telemedicine-related projects. Entities benefiting from the program included consortiums or partnerships of rural hospitals, health care clinics, or other rural health care facilities; major urban facilities also participated in networks to extend their expertise to rural areas using advanced telecommunications. One grant will help support a telemedicine link between a remote hospital in New Mexico to a medical center and university in Albuquerque to provide teleradiology, specialist consultations, and continuing medical education.

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Agencies

| | |
|---------------------------------|---|
| Justice | In 1996, a \$3.2 million telemedicine project involving the Federal Bureau of Prisons and VA was initiated. The Lexington, Kentucky, VA Medical Center will be linked to four federal correctional facilities, including one with a hospital, to provide medical consulting services to inmate patients. A subcontractor will evaluate the project's results to analyze the cost benefits of the application of telemedicine to a correctional environment. |
| NASA | Since it was founded in 1959, NASA has been developing telemedicine technology to monitor and diagnose the condition of its astronauts in space. It has recently used satellites to link medical conferences between the United States and Russia. It also provides some support to private sector research and development. NASA expenditures for telemedicine totaled \$6.6 million for fiscal years 1994-96. |
| National Science Foundation | The National Science Foundation awards grants to advance research in all fields of science. Foundation officials identified projects related to telemedicine in two program areas: (1) biomedical engineering and (2) information, robotics, and intelligence systems. The first program area includes awards of about \$1.4 million to improve the transmission of health information, such as teleradiology. The second program area awarded grants totaling \$5.4 million to advance robotics performance in medical and surgical operations. |
| Appalachian Regional Commission | The Appalachian Regional Commission supports economic development in the rural areas of 12 states. It has awarded grants that sponsor development of telecommunication applications that benefit the public and private sectors. Two projects, operating in western New York and South Carolina, have telemedicine as their major component and received \$0.3 million from the Commission. For example, the New York project supports a consortium of seven hospitals that provides specialty care, emergency medical services, and continuing educational services to member hospitals. |

Comments From the Department of Defense



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

JAN 22 1997

Mr. Mark E. Gebicke
Director, Military Operations and Capabilities Issues
National Security and International Affairs Division
U.S. General Accounting Office
Washington, DC 20548

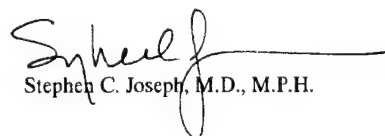
Dear Mr. Gebicke:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report, "TELEMEDICINE: Coordinated Strategy to Push Technology Forward Is Needed," dated December 16, 1996, (GAO Code 703120/OSD Case 1267). The Department generally concurs with the report.

We feel that the report accurately reflects the background of telemedicine, including infrastructure and equipment. The principal findings of the report clearly identify valid issues and the recommendation will contribute to better telemedicine utilization and return on capital investment.

Enclosed are DoD's specific comments on the report and recommendation. Technical comments were provided directly to the GAO staff for their consideration and inclusion in the final report as appropriate. The DoD appreciates the opportunity to comment on the draft report.

Sincerely,


Stephen C. Joseph, M.D., M.P.H.

Enclosure

GAO DRAFT REPORT - DATED DECEMBER 16, 1996
(GAO CODE 703120) OSD CASE 1267

**"TELEMEDICINE: COORDINATED STRATEGY TO PUSH TECHNOLOGY
FORWARD IS NEEDED"**

DEPARTMENT OF DEFENSE COMMENTS

RECOMMENDATION: The GAO recommended that the Secretary of Defense develop and submit to the Congress by February 14, 1998, an overarching telemedicine research and development and operational strategy. The strategy should

- Clearly define the scope of telemedicine in the DoD;
- Establish DoD-wide goals and objectives and identify actions and appropriate milestones for achieving them;
- Prioritize and target near- and long-term investments, especially for goals related to combat casualty care and operations other than war; and
- Clarify roles of the DoD oversight organizations (p. 7, p. 72/GAO Draft Report).

DOD RESPONSE: The DoD concurs with the recommendation as related in the GAO report. For added clarification, we wish to make a few comments on the recommendation.

With the continuing explosion of technological advances that are occurring in medicine, the DoD is not alone in finding itself behind the technological bow wave of telemedicine. Numerous definitions have been applied to telemedicine. One concise definition is needed to define the scope of telemedicine application. One of our first priorities will be the development of a definition and scope of DoD telemedicine.

We agree on the need to establish DoD-wide goals and objectives, as well as prioritize investments, as part of an overarching strategic telemedicine plan. Many of the pieces of this plan are in place. Much has been accomplished over the past year. Goals and objectives have been approved by the Assistant Secretary of Defense (Health Affairs) in the Military Health Services System (MHSS) Strategic Plan, the MHSS Information Management/Information Technology Strategic Plan, and the Composite Health Care System (CHCS) II Mission Needs Statement. In particular, the MHSS has formally adopted the worldwide computer-based patient record as a central program objective for the FY98 Program Objective Memorandum.

With regard to clarifying the roles of DoD oversight organizations, changes are taking place. The Telemedicine Testbed Board of Directors is being incorporated into a more overarching group called the Telemedicine Board Of Directors (TBOD). One of the Surgeons General will serve as the chair of the TBOD. The first chairman will be the Navy Surgeon General. The TBOD will review and approve a revised telemedicine organizational structure at the next board meeting. The oversight for telemedicine deployment will come under the Executive Agent for the Clinical Business Area. The revised telemedicine organizational structure will include a functional tri-service organizational framework. Also, there will be an increased emphasis on modeling, and test and evaluation protocols for systems under development and use of lessons learned from deployed telemedicine applications.

Enclosure

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Comments From the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

JAN 16 1997

Mr. Mark E. Gebicke
Director, Military Operations
and Capabilities Issues
United States General Accounting Office
Washington, D. C. 20548

In Reply Refer To: 10/105E

Dear Mr. Gebicke:

We have reviewed your draft report, *TELEMEDICINE: Coordinated Strategy to Push Technology Forward Needed*, Report No. GAO/NSIAD/HEHS-97-59. Our experience in the use of telemedicine in VA thus far suggests that the future impact of the technology in improving access to medical care and the quality of care could be significant, as is the potential to reduce health care costs. Your report accurately describes the actions currently being taken and those planned by VA to effectively integrate telemedicine technology into the VA health care delivery system.

Your discussion of the barriers faced by public and private sector health care providers in maximizing the effectiveness of this technology is extremely relevant to VA as we initiate development of our strategic plan for telemedicine initiatives. Infrastructure costs; technology and equipment compatibility; and, consideration of clinical and health care requirements in system design are only some of the issues that we need to consider. Our soon to be appointed Chief of Telemedicine will be responsible for addressing these and other concerns in our planning, implementation and evaluation of further application of this technology.

We agree with the recommendations made in the report. We would suggest, however, that it would be beneficial that VA be included by the Department of Defense in its development of a telemedicine operational strategy.

Thank you for the opportunity to review this report. If you have any questions, please contact Mr. Paul C. Gibert, Jr., Director, Reports Review and Analysis Service (105E), Phone: (202) 273-8355, Office of Policy, Planning and Performance (105).

Sincerely,

A handwritten signature in black ink that reads "Kenneth W. Kizer".

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

June 23 1997

Mr. Mark E. Gebicke
Director, Military Operations
and Capabilities Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Gebicke:

The Department has carefully reviewed your draft report entitled, "Telemedicine: Coordinated Strategy to Push Technology Forward Is Needed." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "June Gibbs Brown".

June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Department Comments on the
GAO Draft Report
"Telemedicine: Coordinated Strategy to Push Technology Forward is Needed"

The Department of Health and Human Services (HHS) appreciates the opportunity to review the draft General Accounting Office (GAO) report entitled "TELEMEDICINE: Coordinated Strategy to Push Technology Forward is Needed". The report concludes that the Federal investment in telemedicine is significant but the total dollar amount is unknown, that the Federal government does not have a strategy to maximize the value of its investment in telemedicine, that telemedicine benefits are promising but largely unquantified, and that there are barriers that currently inhibit the adoption of telemedicine. The report includes several recommendations to remedy these problem areas. A major thrust of the findings and recommendations is directed to the Department of Defense (DOD). We have no comments in those areas. Our comments instead concern the activities of the Joint Working Group on Telemedicine (JWGT) and the telemedicine activities of Department agencies.

GENERAL COMMENTS

Recommendations

The report concludes that because the JWGT is already carrying out the Vice President's charge to prepare a comprehensive report on telemedicine issues, it is in a good position to expand its work and take the lead on an overarching strategy. Accordingly, "...GAO recommends that the Vice President direct the JWGT to add State and private representation to develop an intersector telemedicine strategy." While we agree that the JWGT should continue and enhance its highly regarded interagency work in coordination, collaboration and action plans, we do not agree that the JWGT membership should be broadened to include State and private sector representation. We have deep concerns about expanding the JWGT's membership beyond Federal employees. The practical effect of this recommendation would be to turn the JWGT into a new Federal advisory committee.

Specifically, the Federal Advisory Committee Act requires the establishment of a Federal advisory committee whenever one or more agencies form a committee or other group composed in whole or in part of other than full-time officers or employees of the Federal government for the purpose of providing advice or recommendations to one or more agencies or officers of the Federal government on issues or policies which are within the scope of the agencies' responsibilities. Not only is it very difficult to establish a new advisory committee, but such committees are subject to formal rules regarding appointment of members, establishment of charters, publication of notice of meetings, preparation of formal minutes and other procedures. Not only would such requirements alter the nature of the JWGT, but they would place a tremendous burden on scarce Department resources and staff, more than likely resulting in a reduction in frequency of meetings and increased formality of such meetings. It is also unclear who would bear the cost of this expanded structure. Currently, agencies contribute staff time and funds for particular projects, and outside groups and individuals meet with the JWGT at their

own expense. Under an advisory committee structure, private sector and State representatives would be paid for their time and expenses (e.g., travel) as members of the group.

The JWGT is committed to involving representatives from the private sector and States throughout its deliberations in order to gain the widest range of expertise and commitment possible. Outside groups are routinely invited to join the JWGT's deliberations to discuss and work on mutual areas of concern.

As an alternative to the GAO recommendation, we suggest maintaining the current JWGT membership, but adding an annual "Telemedicine Summit" to its activities. The summit would involve representatives from a wide range of private sector and State government organizations. These organizations would review the current state of telemedicine and make specific recommendations to the JWGT on steps to be taken to promote the cost-effective deployment of telemedicine over the coming year. In effect, the summit would help shape the JWGT's work plan. Specific recommendations are likely to include joint Federal/private sector or Federal/State efforts. These efforts would involve ongoing interactions between the private sector and States, and Federal agencies. In effect, the summit and its follow-up activities would achieve the goals of the GAO, namely greater involvement of the private sector and States in JWGT activities, without creating an additional bureaucracy.

Definition and Framework

Clearly this report is about telemedicine. However, the reference on page 13 that "the essence of telemedicine is providing medical information or expertise to patients electronically" might be confused with some of the broader applications that fall under "telehealth." Broadly speaking, the term "telehealth" is often used to refer to a diverse group of health-related activities, such as health professions education, community health education, public health, research, and administration of health services. "Telemedicine," as defined by the Joint Working Group on Telemedicine, refers to a somewhat more narrow definition --the use of electronic communication and information technologies to provide or support clinical care at a distance. This report, which focuses on telemedicine, should be careful not to confuse the concepts in the discussion. If the report references telehealth, it should clearly identify the broader activities being discussed.

Approach and Activities of the Joint Working Group on Telemedicine

The report would benefit from a slightly longer background section that provides more complete information about the JWGT. The Department has shared chapters from reports to the Vice President and the draft Commerce report to Congress with GAO staff. These documents provide extensive background sections on the JWGT that should provide a useful framework for GAO's discussion.

In particular, the JWGT has built its action plan based on a series of previous strategic planning documents that outlined the issues and policy directions to promote the cost-effective

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Appendix V
Comments From the Department of Health
and Human Services

deployment of telemedicine.¹ Many of the documents reviewed were the product of consensus conferences, funded by Federal agencies or the predecessor organization to the JWGT -- the Health Information and Applications Working Group of the Information Infrastructure Task Force Committee on Applications and Technology. These conferences brought together private sector, State, and Federal representatives to outline the challenges and solutions to the effective deployment of telemedicine. In addition to reviewing these documents, the JWGT met with representatives of many groups, including the Council on Competitiveness, the American Telemedicine Association, and the Koop Foundation, to crystallize its work plan.

The JWGT concluded that much had been written about the barriers to telemedicine, and the policies and programs needed to overcome these barriers. These reports were more likely to agree on the nature of the problems than on the solutions. And where agreement appeared to exist, the recommended solutions lacked specificity. The JWGT was formed to move beyond these previous broad strategic planning efforts to the development of very specific actions to address challenges to the effective use of telemedicine. It reports to and coordinates its efforts with the Department's Data Council. In addition to telemedicine, the Council oversees other elements of the Vice President's charge to the Department to coordinate data strategies that promote health applications of the Nation's information infrastructure, including the adoption of health data standards for the collection and transmission of health information, and the establishment of protections to ensure privacy, security, and confidentiality of health information.

Among the specific objectives of the JWGT is coordination of policies and programs across Federal agencies. A variety of activities have been undertaken to minimize duplication in the awarding of grants and contracts by agencies, and to increase coordination of agency evaluations. The bi-weekly meetings provide an excellent forum for exchanging information among Federal agencies and for identifying the need for further activity. Depending on the subject under discussion, outside groups are invited to meet with the JWGT to develop programmatic or policy directions.

The draft GAO report calls for each agency to develop a strategic plan that is coordinated with an overall strategic plan to be developed by the JWGT. At the Department, the telemedicine strategic planning efforts are coordinated through the JWGT and the Data Council. Over the coming year, the Department will be expanding its internal strategic planning process in coordination with its broader activities with the JWGT.

1. Major reports reviewed included: (1) Reaching Rural: Rural Health Travels the Telecommunications Highway (1993); (2) Working Conference on Telemedicine Policy for the NIH (1994); (3) Second Invitational Consensus Conference on Telemedicine and the National Information Infrastructure (1995); (4) Western Governors' Telemedicine Action Report (1995); (5) The Office of Technology Assessment's Bringing Healthcare Online: The Role of Information Technologies (1995); and (6) The Council on Competitiveness' Highway to Health: Transforming U.S. Health Care in the Information Age (1996).

Much of the current activities of the JWGT follow an action plan that builds upon the previous strategic planning efforts discussed above. The work plan, as outlined in the reports to the Vice President, goes far beyond the telemedicine gateway mentioned in the GAO report to address many of the major barriers to telemedicine, including reimbursement, health professional licensure and credentialing, standards, etc. Moreover, increasingly the JWGT will be addressing broader issues of telehealth. It would be desirable for the GAO report to indicate the breadth of the JWGT's current activities, since many of the suggested coordinating functions are already being implemented by the JWGT. It would be more helpful to recommend that individual departments develop coherent approaches in full consultation with each other while encouraging the JWGT to prioritize cross-cutting issues and opportunities both within the public sector and across the public and private sectors. We believe that any grand strategic plan must await the completion of evaluations currently underway. The rate at which all sectors are currently identifying and testing entirely new applications of telemedicine argues against a top-down strategy for defining a research agenda for telemedicine.

While increased coordination is always desirable, the report does not identify any major problems that have resulted from the current level of coordination of Federal telemedicine efforts. Nor does it make a convincing case for specific benefits that are likely to result from a Government-wide telemedicine strategy that goes beyond the already considerable coordination activities undertaken within the High Performance Computing and Communications Program (HPCC) - see below or the JWGT. Several of the benefits which the report expects a Government-wide strategy to produce are already being promoted through the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) implementation activities (health record privacy issues and adoption of health data standards) or are occurring now (e.g. increasing numbers of inter-sector collaborative partnerships in telemedicine).

The Role of the FDA

We believe some of the statements made in the GAO draft report regarding the Food and Drug Administration's (FDA) role in the development of telemedicine policies are imprecise or unduly harsh. For example: "FDA approval policy for medical devices is complicated and lengthy." Or "FDA policy's are out-of-date." or "Manufacturers and others believe that these FDA policies and procedures have limited marketing of new products." Specific revisions are suggested in the page-by-page comments section. The role of the FDA in telemedicine is summarized below.

FDA has responsibility for ensuring that medical devices are safe and effective and minimizing exposure from radiation-emitting electronic products. However, FDA has not yet issued guidance specific to telemedicine, clarifying which telemedicine systems or components fall within its purview and precisely how they are to be regulated. Further, some of FDA's policies are currently undergoing revision, particularly for "pure" computer software, e.g., programs that assist physicians in diagnosing patient conditions. Some manufacturers and others believe that these FDA policies and procedures have limited marketing of new products.

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Comments From the Department of Health
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FDA's role has generated controversy in the telemedicine community. Some believe that telemedicine systems are medical devices in need of FDA clearance. Others believe that (1) these systems require FDA review no more than a telephone or fax machine used to communicate information used in patient diagnostic/treatment and (2) FDA regulation of telemedicine equipment may be unwarranted. FDA's review process for medical devices can be complicated and lengthy, depending on the degree of regulatory control applicable to a particular device.

The FDA device review process has been applied to teleradiology picture archiving and communications systems (PACS) since the late 1970s when they were first introduced into commerce. Such products are cleared under provisions reserved for the lowest regulatory category of devices and which provide for a 90 day review period. A notice of proposed rulemaking published in the December 2, 1996 Federal Register details regulatory changes to further clarify and simplify PACS regulation, including exemption from FDA notification requirements for many medical image storage and communications devices. In addition, the FDA has fostered the development of communications devices. The FDA also has fostered the development of communications standards (working with the American College of Radiology, the National Electrical Manufacturers Association, and the American National Standards Institute among others) and carries on an active research program on imaging performance evaluation in order to simplify the regulation of and promote the safety of these devices.

FDA's review of medical diagnostic software is based on draft guidelines written in 1987 and updated in 1989. According to the Council on Competitiveness' March 1996 report, the approval process imposes an unworkable burden on software developers. In its July 1996 report to the JWGT, FDA stated that major efforts are underway to define and develop software policy. The policy is expected to clarify the factors that determine which software is a medical device and the degree of regulatory scrutiny a medical device must face.

As a first step in developing a policy, FDA cosponsored a workshop with the National Library of Medicine in September 1996 to address its role in the regulation of medical software, including issues related to software distribution, risk-based categorization, and alternatives to traditional FDA review requirements. At that meeting, FDA promised to develop a software policy that is rational and risk-based and to engage the regulated community in the development of that policy in open forums. Further meetings have been scheduled with medical community and manufacturer organizations to continue the dialogue begun at the September 1996 workshop.

The Role of the High Performance Computing and Communications (HPCC) Program

The report should acknowledge the significant role that the interagency HPCC program has played in the coordination of Federal telemedicine research and development activities, beginning at least two years prior to the creation of the JWGT. Most Federal agencies (the Advanced Research Projects Agency at the Department of Defense (DoD), the National Aeronautics and Space Administration (NASA), the National Library of Medicine (NLM) at the

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National Institutes of Health (NIH), the National Institute of Standards and Technology (NIST) and the National Telecommunications and Information Agency (NTIA) at the Department of Commerce, the National Science Foundation (NSF) involved in research and development in telemedicine (chart on page 29 of GAO's draft report) participate in the HPCC program. Other agencies involved in evaluation of telemedicine (the Agency for Health Care Policy (AHCPR) and Research and the Department of Veterans' Affairs (VA)) are also HPCC participants. Health applications of the National Information Infrastructure (NII) have been an HPCC program priority since 1992. HPCC agencies involved in health care applications coordinate their plans at an early stage, participate in the technical evaluation of proposals received by other HPCC agencies, discuss the relative Federal priority of proposals ranked highly in other agencies' technical evaluations, and review proposed funding decisions to avoid undesirable overlap between agencies. In some cases, HPCC agencies issue joint requests for proposals or co-fund projects received by a single HPCC agency. Department participants in the HPCC program also made special efforts to coordinate their telemedicine programs with those of other Department agencies that are not HPCC member agencies. For example, NLM held special discussions with the Health Care Financing Administration's (HCFA) evaluation program staff prior to awarding its first round of telemedicine awards in Fiscal Years 1993/94 and with HCFA, the Office of Rural Health Policy, and also AHCPR before making final funding decisions on its Fiscal Year 1996 awards.

Information Sharing and Dissemination

There is always more that can and should be done to share information about related research, development, and demonstrations funded by Federal agencies, States, and the private sector and telemedicine projects are not an exception to this rule. As the report describes, however, the JWGT has initiatives in this area which are likely to reach fruition in the near future. NLM's online information services are also covering an increasing amount of the published telemedicine literature and descriptions of telemedicine research-in-progress.

Activities of the Office of Rural Health Policy

The report should include a more thorough description of Office of Rural Health Policy (ORHP) activities. The description of the ORHP programs does not capture the breadth of activities being funded by that agency.

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